EXHIBIT 41

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation,	)	MDL No. 15-2666 (JNE/FLN)
	)	VOLUME I
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VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.

LOS ANGELES, CALIFORNIA

TUESDAY, JULY 11, 2017

Job No. 124786

DORIEN SAITO, CSR 12568, CLR

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation,) MDL No. 15-2666 (JNE/FLN)

Videotaped deposition of JONATHAN SAMET, M.D., taken on behalf of Defendants, at 601 South Figueroa Street, Suite 2500, Los Angeles, California 90071, commencing at 10:57 a.m., Tuesday, July 11, 2017, before Dorien Saito, CSR 12568, CLR.

APPEARANCES:

FOR PLAINTIFFS:

CIRESI CONLIN
By: JAN CONLIN, ESQ.
225 South 6th Street
Minneapolis, Minnesota 55402

FOR DEFENDANTS:
BLACKWELL BURKE
By: COREY GORDON, ESQ.
431 South Seventh Street
Minneapolis, Minnesota 55415

ALSO PRESENT:

JORDAN LEADS, Videographer
JONATHAN BORAK
MORDECAI BOONE

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EXHIBITS:

LOS ANGELES, CALIFORNIA; TUESDAY, JULY 11, 2017

10:57 A.M.

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THE VIDEOGRAPHER: This is the start of tape labelled Number 1 of the videotaped deposition of Dr. Jonathan Samet in re Bair Hugger Forced Air Warming Products Liability Litigation in the United States District Court, District of Minnesota, Case Number 15-2666(JNE/FLN).

This deposition is being held at 601 South Figueroa Street, Suite 2500, Los Angeles, California, on Tuesday, July 11 of 2017 at approximately 10:58 a.m.

My name is Jordan Leads from TSG Reporting, Incorporated, and I'm the legal video specialist.

The court reporter is Dorien Saito in association with TSG Reporting.

Will counsel please introduce yourselves.

MR. GORDON: Corey Gordon on behalf of the defendants 3M Alizant. Also with me today is Mordecai Boone, the in-house counsel #M as well as Professor Jonathan Borak, experts.

MS. CONLIN: Jan Conlin and Mike Sacchet

on behalf of the plaintiffs from Ciresi Conlin.

THE VIDEOGRAPHER: Thank you.

THE REPORTER: Would you raise your right hand.

THE WITNESS: (Complies.)

THE REPORTER: Do you so state under penalty of perjury that the testimony you shall give in your deposition shall be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes, I do.

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JONATHAN SAMET, M.D.,

having been duly administered an oath in accordance with CCP 2094, was examined and testified as follows:

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EXAMINATION

BY MR. GORDON:

Q Good morning, Dr. Samet.

A Good morning.

Q As you know from our brief introduction a moment ago, my name is Corey Gordon. And I'll be asking you some questions today about the expert opinions you proffered in the multidistrict litigation pending.

So you've had your deposition taken several times before; is that correct?

A I have in the past, yes.

Q And you've testified as an expert witness in litigation before; is that correct?

A That's correct.

Q Now, I know you've testified as an expert in several cases involving the claims being made against the tobacco industry.

Is that correct?

A That's correct.

Q Have you testified as an expert or offered -- well, strike that.

Have you testified as an expert in any cases involving anything other than tobacco-related claims?

A To my recollection, solely tobacco.

Q And have you offered opinions maybe that didn't lead to you ever having to give a deposition or testimony in court outside of the tobacco arena?

A I would suspect if I looked back across a long career, I've had lawyers contact me about a variety of matters. At most these resulted in conversations but nothing further.

Q I'm guessing that you've probably been frequently asked by lawyers to serve as a consultant

testifying for a witness.
Is that true?
A It seems to happen from time to time.
Q And I'm guessing you probably end up saying no a lot more than you say yes.
Right?
A In general, that would be true, yes.
Q How did you come to be involved in this litigation?
A In this case, I was approached by Michael Ciresi and Jan Conlin and asked if I would review the materials related to Bair Hugger and consider being an expert witness.
Q And you had worked with Mr. Ciresi in connection with the Minnesota tobacco litigation; is that correct?
A That's correct.
Q Was that your first experience as an expert witness, the Minnesota tobacco litigation?
A Probably not. Reaching back in my career, I at least worked with a group of lawyers in San Antonio early in my career, an issue related to asbestos in the renovation of the hotel. But that was probably in the early eighties somewhere.
Q Did that ever result in you giving testimony?

A As I recall, the case was settled out of -- out of court.
Q Before you would have been deposed.
Other than that asbestos case, though, I thought I had read something you had written that led me to believe that the Minnesota tobacco litigation was the first time that you -- maybe the first time you testified in court.
Does that sound right?
A Correct.
Q Okay. And have you -- in the intervening years, about twenty years, have you done any work with the -- Mr. Ciresi or his partners?
A I have not worked with him directly. I've been in touch -- in touch with him from time to time mostly -- mostly saying hello and other things. I remained friends with one of the lawyers from the Minnesota tobacco case.
Q What -- so what was it about this case that prompted you to venture outside the tobacco arena for expert testimony?
A I guess probably two reasons. One was the -- a request from Michael Ciresi and Jan Conlin. Second was the -- you know, my -- my initial understanding on books that -- the specifics of the case. And so I --

so I agreed to do it.
Q Okay. And I take it that you're -- you know, you developed a relationship with Mr. Ciresi and Ms. Conlin over the years such that you have -- consider them friends.
Is that fair?
A Well, I've known Michael Ciresi since the Minnesota litigation, and I've worked with the firm for four years in preparation for the case, so I certainly knew Michael Ciresi well. I met Jan Conlin more recently.
Q If memory serves me correctly, Tom Hamlin was also heavily involved with preparing you?
A I worked closely with Tom Hamlin. He was sort of the -- I guess the person who put -- was the -- was the lead on damages estimation and some of the health-related issues.
Q In this litigation, the Bair Hugger district litigation, what -- what is the expertise that you are offering to the court? How would you characterize it?
A I -- I guess I would characterize it at several levels.
One, I'm not a surgeon, but I have a medical background and -- and did spend two years doing anesthesia.

Second, I've, of course, trained in epidemiology and have put a lot of thought over the years into how one makes judgments about -- about evidence.
Third, I have a great deal of experience around issues related to airborne particles, some -- some understanding of ventilation issues particularly coming out of my work with tobacco and serving on ASHRAE Committee 62. So I worked on a number of issues related to airborne particles.
Q Okay. So I want to talk about those three different buckets. I'll call the middle -- middle bucket epidemiology. We'll put that aside. I want to understand better your -- the expertise that you are proffering in the other areas.
You -- you said you're not a surgeon, but you've done anesthesia for two --
Was it two years?
A That's correct.
Q How long ago was that?
A Oh, quite a while ago. As I said in my report, I was in the Army from '71 to '73 and was made an anesthesiologist after on-the-job training for anesthesiology.
Q Do you consider yourself an expert in

anesthesiology?
A Not based on two years of experience. But I certainly regard myself as familiar with the operating room setting.
Q When was the last time you were in an operating room?
A I'm not sure, frankly. Probably at some point during my clinical career.
Q And what would the time parameters be for your clinical career?
A It extended through 1994.
Q Would you say that you are -- strike that.
If there had been any changes in surgical -- surgical procedures or operating room design or technique issues since 1994, do you -- do you have any reason to think you would have expertise in -- in post-1994 issues?
A Certainly I've made no effort to track what is going on in terms of operating room technology or approaches.
Q And what I'm trying to do is -- is understand the scope of -- of your -- of where your expertise is. I think I have a pretty good idea of what your epidemiology and expertise is, but I want to understand where -- you know, what these other areas

are.
You're not claiming expertise in microbiology, are you?
A I'm certainly familiar with clinical infections, but I'm not a trend microbiologist.
Q What does it mean to be familiar with clinical infections?
A Well, in a many year career in pulmonary medical and general internal medicine, I certainly saw many people with a variety of infections.
Q Do you know the -- for example, the size of various bacteria?
A Oh, I have some general idea of the aerodynamic diameter of bacteria, yes.
Q Okay. Let's take staph bacteria.
What -- what would be the aerodynamic size of a single staph bacteria or the range, the size range?
A I'm not -- I can't say that I can sit here today and for each species give you a range of aerodynamic diameter. It's in the range of submicron and up depending on bacteria form of species.
Q Okay. Would you -- do you consider yourself an expert in nosocomial infections?
A Not specifically, no.
Q How about more broadly, just infectious

diseases?
A Again, I -- I will just say that as -- as part of my general background, I have both clinical experience in pulmonary medicine, critical care medicine. I take care of many people with infections.
And while at Johns Hopkins, my department included one of the world's larger groups of infectious disease epidemiologists, so I had an opportunity to learn something from them.
Q Have you done any epidemiology work in connection with specific infectious processes?
A Oh, I have a few papers on my CV related, actually, but it's certainly not related to this.
Q Let's talk about what the major focus has been. One -- one focus has been cancer; right?
A I'm sorry. Of my work?
Q Of your -- your professional work.
A One has been cancer, correct.
Q Other would be -- another bigger would be other lung diseases such asthma, COPD, in that --
A Well, certainly those would be included as -- as well. And I would add environmental pollutants above -- indoors and outdoors as a critical focus and also cardiovascular disease and sleep.
Q Sleep apnea?

A Sleep apnea.
Q And, again, are there -- are there infectious agents that cause cancer?
A Yes.
Q Have -- have you done any work in -- specifically in infectious agents in cancer?
A I've published on hepatitis B virus and liver cancer in my career.
Q And in the -- okay. And I'm just -- again, I'm trying to understand, you know, your professional activities and how they would relate to infection as opposed to other disease processes -- processes that result in cancer or most cancers or asthma or cardiac conditions.
As you sit here now, can you think of any other peak area of -- of work in your professional career in last twenty or thirty years that you would characterize as being related to infection?
A Some papers related to tuberculosis, along with hepatitis B virus work.
Q Is hepatitis B and tuberculosis would be the main --
A Among -- among the topics that I published, yeah.
Q Have you done any work in the -- specifically

in the area of surgical site infections?
A No, I have not.
Q And I'll ask the broader question first.
So I assume that means you haven't done any professional work in the area of prosthetic joint infections?
A No, not specifically.
Q And you don't -- I'm not asking to insult you. I'm asking just to kind of close the doors on the areas that I'm assuming I don't have to spend a lot of time on.
You don't consider yourself an expert in orthopedics; correct?
A No.
Q You don't consider yourself an expert in mechanical engineering specifically with respect to HVAC systems; correct?
A I don't consider myself an expert, but I did -- I will just repeat it. I did serve on ASHRAE Committee 62, which is a ventilation standards committee.
Q Let's talk about that because I was -- I put that in Bucket 3 anyhow too.
So the -- the work that you did on ASHRAE 62, what -- what did that involve?

A It involved many committee meetings and -- and discussions. And, you know, it is a consensus process organization. So a variety of discussions about ventilation spaces and the amount of ventilation needed particularly in the presence of cigarette smoking.
Q Would it be safe to say that the particular expertise that you brought to the ASHRAE Committee in which you served was your extensive experience in respiratory illnesses in general and secondhand smoke in specific?
A Well, I -- I brought -- I brought that. I also brought the work I had done on indoor air pollution and indoor air pollution measurement and a broad background of -- from discussing these issues with colleagues over the years.
I also edited the Indoor Air Quality Handbook that was published by McGraw-Hill in about 2000 that provided extensive coverage of a variety of -- comprehensive coverage of issues related to air quality. It covered mechanical ventilation systems.
Q When you talk about indoor air quality, I'd like to know what that encompasses.
Secondhand smoke environment of tobacco smoke, that would be something that would impact --

could potentially impact indoor air quality; correct?
A Certainly. Tobacco smoking has been a key source of indoor air pollution.
Q And particulate matter in certain size ranges is -- can be considered something that can degrade indoor air quality; correct?
A Well, certainly particles generally -- I mean, that's a very broad umbrella term -- are among the indoor pollutants of -- of concern, having many sources.
Q And broadly speaking, there -- some particles are capable of causing an infectious process such as a bacterial or viral process; right?
A Right.
Q And there are other that particles that, although they may be potentially damaging in other ways, they don't initiate infection the way that bacteria or viruses do; correct?
A Not all particles are infectious.
Q And in your -- in your professional activities, your research and your publications, have you done any -- any work dealing with particulate matter that you would characterize as infectious other than the stuff we've talked about, hepatitis and tuberculosis?

A I'm sorry. Could you repeat the question.
Q Let me ask -- let me approach it differently.
You've done a lot of research in -- into the issues relating to both indoor and -- and environmental pollution from noninfectious agents, diesel fumes, carbon black, things like that; right?
A I've studied different inhaled agents. Some are particulates, yes.
Q Okay. Have you done --
What -- what percentage of your work has been in -- in looking at inhaled particulates that were infectious agents?
A Oh, I -- I would not say that I focused specifically on infectious agents in inhaled air.
Q Well, would the converse be true, that your focus has primarily been on noninfectious agents?
A Well, I -- I would say sometimes the focus has been general. I mean, that is, particles. And sometimes it's been more specific, characterized into particles in some particular way.
Q Have you done any -- any -- well, take, for example, something like a SARS epidemic -- a SARS epidemic.
Did you do any research that would relate to something like a SARS epidemic?

A I'm not sure I know what you mean.
Q Well, there are certainly epidemiologists who -- whose focus is on the transmission of infectious agents; correct?
A I'm sorry. Some epidemiologists study infectious agents.
Is that the question?
Q Right.
A Yes.
Q And some study the transmission of infectious -- infectious agents through non-airborne routes; correct?
A It would seem to -- I mean, certainly people study infectious agents that may be transmitted by different means and different media, if that's your question.
Q And -- and there are epidemiologists who devote a significant portion of their professional activities to study airborne transmission of infectious agents; right?
A Some do.
Q Okay. And -- and you would not consider yourself -- you wouldn't hold yourself out as -- as that type of epidemiologist, right, one who study -- who -- who devotes a substantial portion of his

professional career studying specifically the transmission of airborne infectious agents?
A That's not been a focus of my career specifically.
Q And I -- I guess at -- has it been a focus of your career generally?
MS. CONLIN: Asked and answered.
THE WITNESS: I'm sorry.
BY MR. GORDON:
Q Well, I said you wouldn't characterize that as a focus of your career. You said not specifically.
So has -- has it been a focus of your career generally.
A In terms of my research specifically, no. In terms of things I read about, you know, just --
For example, the SARS epidemic, I tracked very closely for a variety of reasons, including holding an advisory position with the infectious disease group in Hong Kong.
So I -- I have a general interest in my field of epidemiology do I do work. Specifically research on airborne pathogens, no.
Q And so when you use the term "pathogen" --
A I mean, an organism that causes disease.
Q So you wouldn't consider tobacco smoke to be

an airborne pathogen; right?
A No, I would not.
Q Or diesel fumes?
A In terms of causing infectious disease, no.
Q What -- I'm sorry.
Did you have some professional activities in advising the Hong Kong government during the SARS epidemic?
A No. Following the SARS epidemic, the China University of Hong Kong established an emerging infectious disease center. I was on their advisory board for a couple of years.
Q What did you do in that -- in that advisory board role?
A I guess I did what people do on an advisory board. I went to meetings in Hong Kong. Mainly we discussed their research plans and what they were doing.
Q Getting back to the ASHRAE 62 committee. There were various subcommittees within that; correct?
A There are various subcommittees, working groups.
Q And there were one or more subcommittees or working groups that were looking specifically at hospital HVAC systems; right?

A Actually, the group I was on was concerned with -- was not concerned specifically with hospital systems.
Q Okay. It saves some time. Thanks.
So your actual work really didn't involve hospital HVAC systems?
A It involved commercial buildings, but not hospital HVAC systems.
Q And, again, the focus there would be on general air quality, not control of airborne pathogens specifically?
A That's correct. It was on the level of ventilation to achieve an acceptable air quality level.
Q And was there like a name of the group or the working group or the subcommittee that you were on?
A Well, I will say I was on one subgroup that resulted in a paper that addressed sort of issues around defining acceptable air quality.
The group was made up of some of the members who had health expertise. There were various other groups related to the tobacco smoking issue.
Q So the -- the -- whatever the committee might have been called, you -- the end result was something that sought in the -- in the ASHRAE consensus approach

to define what acceptable air quality standards were; is that right?
A Well, one issue that we took on was whether such a definition was achievable.
Q Did you conclude that it was?
A We concluded that it was complex. That's essentially what our paper says.
Q And correct me if I'm wrong. But the focus would have been on commercial buildings; is that correct?
A Correct. Commercial public buildings, yes.
Q Okay. And did you -- did -- did your contribution result -- strike that.
Did ASHRAE ultimately promulgate any definitions of acceptable indoor air quality for commercial buildings?
A Well, I will say that one follow-up was that I chaired a committee for ASHRAE on secondhand smoke that was a position document that said if there were smoking in buildings, that acceptable air quality could not be achieved.
Q Okay. Did that subcommittee that you chaired look at airborne pathogens?
A No, it did not.
Q Is there anything about the activities that

you did in connection with ASHRAE that you believe gives you expertise in engineering issues related to control of airborne pathogens?
A I think by sitting with a group of ventilation engineers for several years I gained a general background in the operation of air-handling systems within buildings.
Q Do you feel that you have -- that carries over into giving you insight into air-handling systems in ultraclean operating theaters in hospitals?
A Again, I don't think -- to -- to your point not specifically. But as I said, a general background.
Q Let's talk about your -- your activities as an epidemiologist.
Broadly speaking, how do you define what it -- what it is that you do as an epidemiologist?
A I'm sorry. That's such a broadly speaking question, I'm not sure what you're trying to ask me.
Q Okay. Well, you don't, for example, design medical devices; right?
A Medical --
Q Medical devices.
A As an epidemiologist, no.
Q You don't -- well, strike that.

Would you characterize your activities in the field of epidemiology to be primarily focused on causal relationships between the environmental exposures and adverse health outcomes in pop- -- in large populations?
A I'm not sure I would describe what I do in such a limited fashion. There are many other aspects of the work I do.
Q Have you ever had been asked to consult with a hospital in trying to identify or control an infectious outbreak?
A No, I have not.
Q Have you ever studied or written anything about hospital infectious outbreaks?
A No, I have not.
MR. GORDON: Let me -- do you have exhibit stickers?
To speed things up, I'll just write the numbers on them.
Dr. Samet, let me show you what's been marked as Samet Exhibit 1.
(The aforementioned document was marked Exhibit 1 for identification by the reporter.)
///

BY MR. GORDON:
Q And I will -- I want to first establish what this is. I will represent to you that I did not include your CV, but I tried to include the text of your report; the -- your Exhibit C, the materials considered; and Exhibit D, the state of condensation. So I'm not representing this is the complete report that you submitted, all the -- all the materials that you submitted.
But does this appear -- does Exhibit 1 --
First of all, does that contain your entire expert opinion or your opinions?
A As submitted, yes.
Q Okay. And so -- and that would be the first twenty-four page of Exhibit 1; is that right?
A Correct.
Q And Exhibit C, which I believe is fourteen pages, and it's entitled "Materials Considered"; is that right?
A That's correct.
Q So I want to spend a little time on Exhibit C for -- just for right now. Exhibit C is a listing of all of the materials that you considered for -- specifically for purposes of rendering your opinions that are set forth? There's twenty-four pages.

A Yeah. Up to -- up to the time of March 30.
Q Up to the time of March 30. You anticipated my next question.
Subsequent to March 30, have you reviewed any other materials that have in any way impacted your opinions in this matter?
A I've seen one additional peer reviewed publication by Augustine describing three -- interrupted time series studies of fecal infections in three institutions with a switch from forced-air warming to conductive warming.
Q Had you ever seen that publication before or the journal in which it was -- well, strike that.
You said it was a peer reviewed publication.
How did you determine that?
A My understanding was that it was a peer reviewed journal.
Q Where did that understanding come from?
A I guess acceptance that it was in the journal that I thought was peer reviewed.
Q Did you do anything to investigate whether it was a peer reviewed journal?
A Specifically, no.
Q Did you do anything to investigate whether it was --

Well, did you do anything to determine what -- whether the journal in which it was published was one that was widely read or -- or well respected in the -- in any particular medical fields?
A As I -- as I recall, the paper did have both a public -- sorry -- a submission and an acceptance date, which would imply to me that it was, in fact, peer reviewed.
I'm not specifically familiar with that journal versus other journals in the -- in that general area.
Q Have you -- you published hundreds of papers, haven't you?
A I've published hundreds of papers.
Q Have you ever had to pay to publish them?
A I'm sorry?
Q Have you ever had to pay to publish any of your publications?
A I would have to think because in today's online journal world, you sometimes pay. And whether some of my papers have to be in Class One [phonetic] or some of the journals where you pay. I'd have to look. That's something that's happening in today's publication world.
Q As you sit here today, can you remember

having yourself to pay an online publisher to publish a paper you had authored co-authored?
A I would have to look because I think some of our recent online papers had been in such journals regarding global health, but I -- I can't pull up the details of that today.
Q This Augustine publication that you -- that you read, how did you come to learn about its existence?
A I actually learned about it from, uh, Jan Conlin.
Q Okay. And how long ago did you read it?
A Oh, initially, within the last ten days probably.
Q Did you -- one of the things that you indicated that you reviewed prior to rendering your opinions in this matter was the -- hold on. I misspoke. I apologize. I withdraw that.
Have you ever read the deposition of Scott Augustine?
A Well, I -- I will say that I have seen a number of depositions. Would -- in all honestly, I have difficult saying this is the reliance list here in terms of what I looked at.
Q I -- I'm sorry. Could you explain that. So

Exhibit C is not a comprehensive --
A No. Exhibit C is what I looked at. I kind of --
Q Okay.
A Yeah.
Q And I assume you tried to be as comprehensive as possible.
A Yes. And reviewed the materials that I had in preparing this list.
Q I don't see the deposition of Scott Augustine included in the reliance materials.
Is that -- is that an oversight, or is that -- is that -- is it accurate that you did not read Dr. Augustine's deposition?
A Well, the -- the only thing I'm saying is that in preparing this list, we went through everything that was on hand in my office and had been sent to me. So unless we missed it, it's on here.
Q As you sit here today, do you have any independent recollection of having reviewed either the full Augustine transcript or any portions of his actual testimony?
A I -- I mean, again, I can't swear now having read through or at least skimmed through it. So many of these depositions. That one specifically.

Q Did you -- do you know if you had occasion to look at any of the exhibits that were marked at the Augustine deposition?
A I don't know.
Q Well, let me be more specific.
Do you recall when you saw this Augustine paper that you brought up that you said you saw maybe ten days ago, when you looked at it, did -- did you look -- did anything trigger a thought in your mind that "Gee, this looks like something I've already" -- "at least part of something that I've already seen before"?
A Not specifically, no.
Q That appeared to be like brand-new material?
A (Nodding head.) Yes.
Q So as you sit here today, do you have any information about the background of how that Augustine study came to be prepared, the underlying data, any -- any -- any information about it other than what was represented by Dr. Augustine in the publication itself?
A To my -- to my memory, my -- my understanding, that paper is based on reading it.
Q Has that paper had any impact on your opinions?

A I regard the paper as another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison.
Q You -- ultimately, your opinion in -- the -- the sort of the bottom line general opinion was that you concluded that the -- based on your epidemiological expertise, that the Bair Hugger -- use of the Bair Hugger in orthopedic surgery is a substantial contributing cause to the development of periprosthetic joint infection; is that right?
A That's the last sentence of my report, page 17.
Q I want to ask about this phrase "substantial contributing cause."
Is that a concept that's used in the field of epidemiology?
A Well, I think there are a number of different approaches taken to describe causation, strength of causation, contribution to cause. There's -- so I -- it's -- it's a word that I have seen used or a phrase that I've seen.
Q It's not a phrase that you use, though; right?
A I think it would depend on the context.

If -- this refers to the magnitude of excess risk. So it's a description based on the odds ratio of the strength of association.
Q You've written or co-authored hundreds of -- of papers and studies that looked at odds ratios, attributable risk, and things like that, and drawn causal conclusions; right?
A In -- in -- in various activities and not specifically in the context of my papers. I've worked on reports and other expert documents that had causal conditions.
Q Would it surprise you that not one of your publications has ever used the phrase "substantial contributing cause"?
A I -- I'm not sure what the basis for your statement is, but...
Q Would you -- would it surprise you that if you were to search everything that you've written, that the phrase "substantial contributing cause," that exact phrase, never appears in anything that you've authored or co-authored?
A I really don't -- don't -- just don't have an opinion.
Q Well, wouldn't you agree that -- that the notion of something being a substantial contributing

cause is not something that -- that you, at least in your professional activities as an epidemiologist, have looked at or -- or used as a reference point?
MS. CONLIN: Objection as to form --
THE WITNESS: Well --
MS. CONLIN: -- it mischaracterizes his testimony.
THE WITNESS: Well, again, I think in terms of the question of causation, there are two -- two issues.
One is, Does an agent cause whatever the outcome is that's being considered?
And the second is, What's the magnitude of its contribution to causation?
So certainly I've written about both aspects of causation; the question of Is an agent causal? And then second, What is its contribution?
BY MR. GORDON:
Q Well, what constitutes a substantial contributing cause as opposed to a contributing cause that isn't substantial?
A Well, you know, again, I don't have strict numerical criteria.
But here I think the basis for the

calculation is the simple attributable risk of the exposed which precedes the facts of the substantial contributing cause. That -- you know, that estimate is 74 percent as -- as stated in the sentence on page 17.

Q Would an attributable risk of 10 percent be a substantial contributing cause in your opinion?

MS. CONLIN: Objection; it calls for speculation.

THE WITNESS: I mean, I -- I -- again, 10 percent is substantially lower than 74 percent.

BY MR. GORDON:

Q As an epidemiologist, is there some either absolute number or -- or -- or general range of attributable risk that you would characterize as either substantial or not substantial?

A I don't -- I don't have bottom line cutoffs, if that's your question.

Q Well, I'm trying to -- my question is, How did you determine that -- that the attributable risk that you found was a substantial contributing cause as opposed to simply a contributing cause?

A Well, that was based on this estimate of 74 percent of the attributable risk of the exposed.

Q And the attributable risk is derived from the

relative risk; right?

A It's based on the relative risk of the exposed, correct.

Q And that's just simply a mathematical -- arithmetic computation; right?

A As shown here, it was a straightforward calculation.

Q But deriving a number for attributable risk when you have a relative risk, that's just a standard arithmetic calculation, RR minus -- divided by --

A Correct. That's provided in the sentence before.

Q So coming up with an attributable risk, that's not -- that doesn't involved any -- the application of any expertise once you provided relative risk; right? It doesn't involve any judgment, I should say?

A Well, it's a standard calculation.

Q Okay. So I -- once somebody derives a relative risk and the attributable risk is calculated either by you or somebody else, determining whether the attributable risk is substantial or not, that's -- that's just a judgment call for you? Is that --

A Well, I --

Q -- what you're saying?

A I mean, again, here the figure is 74 -- 74 percent, which is, you know, the majority. So -- of the risk of the exposed. So in that case, you know, the word "substantial" seemed applicable.

Q You have -- and that's -- we're going to be talking quite a bit today about the McGovern paper, and so let's define that.

You -- one of the items upon which your report is based was the -- a paper published in 2011 that is listed as Item Number 49 on your materials considered list; is that correct? McGovern, Albrecht, Belani, et al.

A That's right.

Q "Forced-air warming and ultra-clean ventilation do not mix: An investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics."

A Correct.

Q So when I -- when I refer to the McGovern study -- we could -- at some point we could mark it. Probably will.

But is -- is that this reference, Number 49, that I'm referring to, sir?

A That's fine.

Q Okay. And that -- the -- the relative risk

of 3.8 from which you derive attributable risk of 74 percent, that came out of the McGovern paper; right?

A That is correct.

Q And you have looked at all of the underlying raw data that had -- hadn't been made available to anyone for that McGovern paper; right?

A I did not look at the actual raw data.

Q You never looked at it?

A I have seen the representations of what is said to be the raw data in discussions of it. But I did not directly examine, count, or compile the raw data.

Q I don't understand what you mean.

What -- what -- have you seen the -- what you're characterizing as representations of what --

How -- how did you phrase that?

A I've seen printouts of data sets that are attributed to being perhaps the original data. I believe I saw that in Albrecht's report, perhaps.

Q Well, let's go back to your materials considered list. I want to understand something about that.

For the list of -- of depositions, the first page of Exhibit C, you list nineteen depositions;

right?
A I'm not --
Q They're numbered, I think.
A Sorry. Which page is this?
Q Page 1 of Exhibit --
MS. CONLIN: C.
BY MR. GORDON:
Q -- C.
A Okay.
Q So there are -- you list nineteen deposition transcripts and exhibits.
A That's correct.
Q Now, for some of the transcripts, you -- you identified the -- the deponent, the date, and you say final deposition transcript and Exhibits 1 through blank, whatever they put on those. Like Gary Hansen or Al Van Buren [phonetic], Numbers 5 and 6.
Is that right?
A That's correct.
Q But for several of these, you don't say anything about exhibits. You just say, for example, Example Number 1, Kumar Belani, September 7, 2016, final deposition transcript.
A Yes.
Q I don't want to assume anything.

Where you don't list exhibits, does that mean you didn't review the exhibits if there were any or that you just didn't list that?
A This is a list of material -- I had materials that were provided by Ciresi Conlin, and -- and this is a straightforward compilation of what was on hand done by my research assistant.
Q So your assistant -- this was a review of material by a research assistant?
A Sorry.
Q In reviewing the material that -- on which you relied for your report, you were assisted by a research assistant?
A No. I had a research assistant to organize these materials and try to keep everything organized, if you will.
Q Okay. Well, can -- would it be correct to conclude that if there are no exhibits listed for a particular deponent, such as Kumar Belani, that would mean that you didn't review any exhibits, you just reviewed the transcript?
A That would be correct.
Q Okay.
A These are the materials we had.
Q And I'm curious because you made reference to

Albrecht, the exhibit that you described as the printout of a data set. You're listing the two deposition transcripts for Mark Albrecht. It showed -- it doesn't list any exhibits.
A Yeah. No. These were provided as -- to me as background in reviewing the reports from Drs. Holford and Borak.
Q So prior to rendering your opinion, you hadn't seen --
A That's correct.
Q -- the data set?
A That's correct. It's more recently that saw a thick compilation of the printout.
Q Okay.
A What was said to be a compilation.
Q Okay. Just so we're clear. So when you read -- or -- excuse me.
When you rendered your opinion on March 30th, you had not looked at anything that purported to be underlying raw data for the McGovern paper; is that correct?
A I had not.
Q So -- so if a representation was made to the court that you looked at all the evidence, all the underlying raw data, and concluded that McGovern is an

absolutely valid study, that would be not be a correct representation --
MS. CONLIN: Objection --
BY MR. GORDON:
Q -- correct?
MS. CONLIN: -- as to --
THE WITNESS: Again, as I -- as I said, up to the time of March 30, I had not seen raw data from the McGovern study.
BY MR. GORDON:
Q And you wouldn't have analyzed it, obviously, then to make a determination as of March 30 that the McGovern study was an absolutely valid study; right?
A Well, I -- the McGovern study was published in the peer reviewed literature. Again, reanalysis of the raw data is not necessarily a requisite standard for validity.
Q And you didn't do any reanalysis; correct?
A That's correct.
Q Did you make any independent determination that the McGovern paper was a valid study?
A I guess I'm not sure what you mean by a "valid study."
Q Does the concept of a valid study versus an invalid study have any meaning in the field of

epidemiology?
A Again, there are many, many aspects of the manuscript that one would look at to decide about what it shows.
I just simply don't classify things as a valid study or an invalid study based on -- in the way I think you're using these terms.
Q Well, I'm just --
Would it be fair to say that you did not independently come to any conclusion regarding the validity of the McGovern study?
A Okay. Again, I'm a little puzzled by the word "validity" as you -- as you used it. I have not carefully read what was in the published manuscript and -- and interpreted it.
Q Well, I'm just -- I'm just trying to understand. Somebody represented to the court in this case that you, Dr. Samet, had reviewed all the underlying raw data and concluded that McGovern -- that McGovern was an absolutely valid study.
We've already established that you -- that would be wrong because you didn't look at the underlying data, and that would also be wrong because the concept of being an absolutely valid study doesn't have any -- any significance, it doesn't mean

anything; right?
A I -- I really don't understand what you're saying. I'm not sure I know what you mean by "absolutely valid."
Q It sort of doesn't matter what I'm --
Is -- is there any meaning of that phrase that you would use that would allow you to say "Well, yes, I did. I did draw an independent conclusion that it was an absolutely valid study"?
A Again, if I -- to use my words, I would look for the study and the conclusion and the methodology as described and the potential for there to be a source and a debate about bias.
Q And as of March 30 when you rendered your opinions in this case, you had concluded that there were no sources of bias; is that right?
A There were no major sources.
Q No major sources of bias.
Did you determine there were any minor sources?
A Well, I -- I think -- in epidemiology and doing observational studies, there may be sources of bias that are, you know, there but not well-described. But here at least I did not see any major sources of bias.

Q And how would you character- --
What would you characterize as a major source of bias? I want to use the right phraseology.
A Well, I mean, the -- the issues that affect any observational study are threefold. One is confounding, one is problems in measurement, and the third is selection bias.
Q And by "measurement," do you mean quantification or tabulation or both?
A Error in measurement.
Q Would tabulation error be considered a measurement error?
A It could be if anything was tabulated.
Q And what -- what do you mean by selection bias?
A Selection bias is a form of bias that arises from differential participation or dropout from the study in a way that distorts the exposure-outcome relationship.
Q And going back to the first potential source of major bias, confounders.
You concluded that there were no confounders that would rise to the level of major bias in the McGovern study; right?
A That's correct. I concluded that there was

no source of confounders that would have led to the estimated level of bias.
Q And the only sources of confounding that you mentioned in your report were the prophylactic antibiotic regimen and the thromboprophylaxis regimen; correct?
A Correct.
Q Did you look at any other potential confounders in the McGovern study besides antibiotics and thromboprophylaxis?
A Well, from the information provided -- let -- let me step back.
A confounder here would have to be something that differed in the two time periods of observation, the Bair Hugger period and the conductive warming period. And that in itself was a risk factor for deep joint infection.
So that -- that is a requirement. And from the information available in the publication, there was not an indication of other confounders.
Q Based on what was actually in the paper?
A Based on what was actually in the paper.
And the other comment I would make is, aside from the transition period -- the two-month transition period, any potential temporal confounder would have

to change rather quickly to introduce bias.
Q And in order for you to have determined that something is a confounder -- correct me if I'm wrong. But it's your -- your expert opinion that a particular risk factor has to independently achieve statistical significance. Otherwise, it -- it is disregarded, it doesn't have an impact, it has no results.
A It does not necessarily have to achieve statistical significance to be a confounder.
Q So something that isn't -- it potentially impacts an outcome, but doesn't do so in a statistically significant way could nevertheless confound a study?
A If it met the criteria of being associated with the factor and was also an independent risk factor on its own.
Q If bias being -- when you say being associated with it and an independent risk factor on its own, would the association have to be statistically significant in order for it to be considered a --
A I'm sorry. Which association?
Q Just hypothetically. If you're looking at the question of does X cause Y, and you compared two groups, one that was exposed to X and one that was not

exposed to X, and the outcome Y.
That's pretty standard epidemiological study; right?
A Well, it might be a standard data set. That's correct.
Q Okay. And -- and if --
THE WITNESS: Jan.
(The witness handing glass to Ms. Conlin.)
BY MR. GORDON:
Q -- some of the people in one group that you were comparing to also had an exposure to Z, factor Z, and the people in the group to which you were preparing that group had no exposure to Z, it's possible that Z could be an independent risk factor for outcome Y; right?
A Well, that would depend on what is known about Z, and is it, in fact, a predictor of a risk factor for the outcome.
Q Okay. Let's -- and that's what I'm talking -- I want to talk about Z. For it to be a risk factor that you would consider a confounder that could give rise to concerns of major bias, does Z have to be --
Well, first of all, it would have to be an

independent risk factor, right --
A That's correct.
Q -- because Z has an association with Y independent of X; right?
A I'm getting a little confused by X, Y, and Z, but yes.
Q Okay. Does Z have to be associated with the outcome Y independently but in a statistically significant way in order for it to be considered a potential confounder that would give rise to concerns of substantial bias?
A I'm sorry. I think -- if you don't mind, I'll try and say it better.
Q Please put it in your words.
A That -- that our hypothetical confounder Z -- if I understand, your question is, Is it requisite for confounding that it be statistically significantly associated with X? Is that --
Q I think the outcome was Y, but that's fine.
A Y.
Q Whatever --
A Y. All right. Probably better to start over.
Q You know what, let's -- let's stop the algebra. I apologize that, for getting us off on

that.
One of the issues you looked at was whether use of rivaroxaban as a proper prophylaxis could have been a -- a confounder in your medical opinion; correct?
A Yes, that's right.
Q Rivarox- -- rivaroxaban was used for part of the Bair Hugger only period but not at all in the HotDog period; right?
A Correct.
Q So if rivaroxaban was an independent risk -- risk factor for the outcome of -- of joint infections, it could be a confounder to any causal determination of -- of the impact of Bair Hugger versus HotDog; right?
A I -- in responding, I want to emphasize that you said if it is a risk factor for deep joint infection, which I'm not aware that that is actually established.
That is a high -- the requisite requirement for -- for a confounder is it would be an independent risk factor, which is a matter of judgment based on, you know, what is known in general about the potential confounder.
Q And -- and -- well, specifically in the case

of rivaroxaban, you determined that it was not a risk factor, right -- I mean, the benefit risk factor?

A Excuse me.

It seems -- it seems unlikely. I mean, as I thought about this, I struggled with why a -- an agent that's a thromboprophylactic agent would increase the experience of infection, particularly when administered postsurgery.

So this was a judgment that's, you know, perhaps not fully spelled out here, but it was based on what was within the data set and other considerations.

Q Okay. And -- and, obviously, I can't know what the considerations were that -- that led you to the conclusion that weren't in your report. So, you know, now is my time to get -- to ask you these questions. I --

Please tell me everything you considered in coming to the judgment that in the McGovern study the use of rivaroxaban for seven months in the Bair Hugger only period was not an independent risk factor for developing joint infection.

A Well, you know, again, I -- as I -- as I said, I questioned how an agent used for thromboprophylaxis would plausibly increase risk for -

for infection.

I looked at -- I think it was a Jensen publication that provides some -- some relevant information.

And to my understanding, this is an agent that is also administered after surgery is completed. Of course there's a risk for -- for bleeding, which, to me at least, again leads to questions about the -- the plausibility of it being a, quote, "independent risk factor."

I recognize that different -- as you said, different agents for thromboprophylaxis were used at different points in this time series.

Q You mentioned Jensen.

Did you conduct any independent research into the medical literature to see if anyone else besides the Jensen, et al., authors had looked at whether rivaroxaban as a thromboprophylactic agent in joint replacements could -- could impact infections?

A Well, you know, again, there are, as I recall, some other relevant studies. I think the record study -- there was a group of investigations.

I mean, you know, this -- in a sense, it's hard to study. Deep joint infection is not particularly common, making it difficult to do

well-powered studies.

Q Was the McGovern study well-powered in your opinion?

A That's a question that I would not answer that way. I mean, it's a -- a somewhat limited period of observation for an event that is not uncommon -- I'm sorry -- that is not common. The results, as presented in the original report, were statistically significant.

Q I may have misread your -- your opinions, so I want to clarify my understanding.

Was one of the reasons you came to the conclusion that rivaroxaban was not an independent risk factor was the fact that the Jensen paper concluded that the increase that they reported in joint infections during the rivaroxaban period was -- did not reach a statistical significance?

A I -- you know again that's certainly a part of the story that -- to look at. And the outcome they had admittedly for deep joint infection might have been subject to some misclassification.

But as I recall, it was a -- a grouping. But it certainly did not provide strong evidence that rivaroxaban/Xarelto was a strong -- an independent risk factor.

Q Did it provide -- do you recall, did it provide evidence that rivaroxaban wasn't at all a risk factor, whether it was strong or weak?

A Studies don't usually provide evidence that something is, quote, "not at all a risk factor." To be -- I think I mentioned in the context safety in here, that would require a very narrow -- a -- a striking degree of precision around an estimate to say something is, quote, "absolutely safe."

Q Putting aside the Jensen study for a moment, did you do any research into the medical literature to see if there were any other studies on the impact of rivaroxaban on joint infections in joint replacement surgeries?

A I did not do a systematic search.

Q Do you do a nonsystematic search?

A I -- you know, again, I saw several articles. But I did not do a systematic review, if that's the question.

Q And all the several articles that you saw, would they all be listed on Exhibit C?

A At least two of the main ones, the Jensen and the Jameson, yes.

Q And as you look over this list of materials, is there anything else besides Jensen and Jameson that

you reviewed that in any way addressed the issue of whether rivaroxaban could be an independent risk factor for joint infection?

A As I -- as I said, beyond those two, I did not do a systematic search to this point.

Q Okay. How is it that you chose to review and rely on Jensen and Jameson?

A Well, I -- in the -- in -- on page 9, I provided a list of the search strategies of where articles came from. And similar to this net that arose, I can't say specifically which approach, which search resulted in those two articles. But the strategy is laid out there.

Q Okay. And let's -- I want to -- I want to be clear. Is it your testimony that every single one of the papers that cropped up or -- strike that.

Is it your testimony that all ninety-six of the publications that you list in Exhibit C were independently gathered by you as a result of these search parameters that you list on page 9 of your report?

A Well, page 9 describes the whole strategy, which included the literature that did come from Ciresi and Conlin, my own literature searches, and expert reports that I read.

Q And thank you for clarifying that.

Some of the literature upon which you relied was provided to you by Ciresi Conlin; right?

A And, you know, again, I can't speak to this directly. I'm sure probably the same papers were identified in the literature searches.

Q Would it surprise you if you were to run a PubMed search using all of the search terms on Exhibit 9, that would you not find either the Jensen or the Jameson paper?

A As I said, I don't know which were found by which means.

Q So as -- right as you sit here today, you have no independent basis for -- for saying that either the Jensen or the Jameson paper did or did not come out of your own search efforts as set forth in Exhibit -- page 9 versus something that was provided to you by Ciresi Conlin?

A As a general comment, I did not tag things one way or the other.

Q And unless it was --

A Just one second. One second. I lost my mike.

Q Oops. I'm sorry.

MR. GORDON: And by the way, we've been

going for a while. If you want to take a break, we can --

THE WITNESS: Well, that would probably --

MS. CONLIN: That's fine.

THE WITNESS: -- you know, what we're doing.

MR. GORDON: This isn't a marathon.

MS. CONLIN: I don't know what --

THE WITNESS: That's good to know. What?

MS. CONLIN: Let's -- why don't we take a five-minute break. I mean --

MR. GORDON: Yeah.

MS. CONLIN: -- when you get to a convenient spot, that be fine with me.

THE WITNESS: Actually, five minutes would be --

MS. CONLIN: Okay. That's fine.

THE VIDEOGRAPHER: The time is 12:12 p.m. We are off the record.

(A brief recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 12:27 p.m.

MR. GORDON: I just want to -- we've been

talking about it a lot, so I just wanted to -- we'll mark it separately so there's no question what we're talking about.

I'll show you what's been marked Samet Exhibit 2. It was also previously marked as Albrecht Exhibit 8.

(The aforementioned document was marked Exhibit 2 for identification by the reporter.)

BY MR. GORDON:

Q Is -- Samet Exhibit 2, is that the McGovern paper that we've been talking about?

A Yes, it is.

Q There are actually two components to this study, correct, of mechanistic components looking at bubbles and airflow and then the observation of the components?

A That's correct.

Q And you -- and your conclusions relating to the odds ratio, the attributable risk, those things in your report, that's are all based on the observational component of the McGovern paper that we've now marked as Exhibit 2?

A The quantitative discussions based on the observational component, correct.

Q And one of the reasons you conclude that the odds ratio that is reported, the relative risk that is reported is not influenced by any confounders is the fact that it is a strong association; is that correct?
A In part, yes.
Q Anywhere in part.
And tell me -- well, strike that.
Would you -- would you agree that -- that generally in the epidemiological literature, associations are usually categorized as weak, moderate, or strong?
A I -- people may do that. I personally don't.
Q You don't?
A No.
Q Okay. So is it binary for you? Something is -- an association is either strong or it's not strong?
A I think the numbers speak for themselves.
Q Well, what's a strong association?
A I -- I -- again, I rely not on adjective descriptors in -- in general but on the description of what the actual estimate is.
Q So would you rely on 3. -- a relative risk of 3.8 as a -- as evidence of a strong association? That a relative risk of 3.8, in your opinion, constitutes

based on association; is that right?
A Actually, I'm not sure I applied the word "strong." I'd have to look through my report.
(Witness reviewing document.)
THE WITNESS: I discussed strength of association on page 16. I did not -- I said moderately. It says "moderately strong."
Page 16.
BY MR. GORDON:
Q Moderately strong association.
Okay. Tell me, in your stratification of -- of a strength of association, what -- what are the different categories? Is there --
A Again --
Q Is it moderately strong? You know, strongly strong? Weakly strong? I -- I'm not --
A That's why. I just can't give you a Jonathan Samet classification where I have a set of standard descriptors I would use.
Q Okay. But to you, 3.8 is moderately strong?
A Correct.
Q And would -- would you consider a 3. -- if somebody said "Dr. Samet, I've got a" -- "got some observation study that concluded that there was a relative risk of 3.7," do you think that kind of

eliminates the possibility of -- of confounders? Would you say that 3.7 was a moderately strong association that would give you reason to -- a comfort level that there -- that that's not a result of confounding?
A I -- it's not so simple a question. It really depends -- it depends on the relevant confounder set and how strong confounders might be as -- as risk factors for the outcome of it.
Q So it's not be the number in the abstract that allows to you decide whether it's a moderately strong association or not? There are some other factors that you consider in conjunction with the actual relative risk number?
A I'm sorry. You're speaking to the strength of the relative risk or confounding?
Q Well, I'm focusing on -- on page 16 where you say (reading):
"With respect to the Hill criteria" -- "Hill postulates, that with respect to strength of association, the available observational evidence indicates a moderately strong association."
And you discussed McGovern and say

(reading):
"The relative risk is estimated at 3.8."
And, you know, I -- I'm -- I'm pretty sure I saw it somewhere else. You did link that.
Yeah, I -- I think what I was -- thank you for pointing me to that. What I was thinking of is on page 12 where you said that (reading):
"A more general argument against confounding can also be made. In setting aside whether the antibiotics and/or thromboprophylaxis were truly confounding, the magnitude of the association, 3.8 odds ratio reported by McGovern, et al., deserves consideration."
You say that (reading):
"Such confounding is not only unlikely but is not supported by the evidence considered above and reviewed by Professor Nachtsheim and Drs. McGovern and Reed."
Right?
A Correct.

Q By the way, you didn't mention the consideration given to that specific question by Mr. Albrecht.

Had you read his deposition, either of the transcript days, at the time you wrote this?

A I -- I -- you know, again, I'm just going to have to plead fuzziness on what I read and when. I just simply --

Q Fair enough.

A -- can't tell you.

Q Do you know who Mr. Albrecht was?

A I heard -- I understand that he's an analyst and that he had -- that -- I don't know his full professional history, but I've heard a little bit about him.

Q Well, did you -- did --

Were you aware that he did the statistical analysis in the McGovern paper?

A I'm aware of that, yes.

Q And were you aware that he worked for Scott Augustine's company, Augustine Biomedical?

A I'm aware that he did. I don't know his full history. I -- I understand that he did. And perhaps now he's not. I don't know.

Q Okay. Well, do you know who --

First of all, do you know who Scott Augustine is in relationship to the Bair Hugger?

A My -- I think I do, yes.

Q What's your understanding?

A My understanding is he was the original developer of the Bair Hugger device.

Q Okay. And what's your understanding of what --

Is he still -- still involved with the mark- -- manufacturing and marketing of the design? Anything to do with -- with the Bair Hugger device?

A No.

Q Do you know what he does now?

A I -- I believe he has his own company.

Q What does it do?

A I think it makes another warming device.

Q Do you know what it's called?

A I think it's called the HotDog or something equivalent.

Q That's -- and that's -- that -- that was the comparatory device in the McGovern paper; right?

A Correct.

Q Do you know why Scott Augustine left the company that he started that made Bair Hugger?

A No.

Q You were never told that he was convicted of Medicaid fraud by the company?

A I don't know his history.

Q And have you -- you haven't read his deposition; right?

A It's not -- it's not -- it's not listed.

Q Okay. We'll talk about it then later.

The -- in your -- on page 12 when -- you're talking about that -- your decision to set aside whether the anti- -- the antibiotics and/or thromboprophylaxis is truly confounding; right?

A That is correct.

Q Okay. You used -- again, I want to focus in on that phrase "and/or."

You weren't just considering antibiotics alone as a risk factor -- independent risk factor and thromboprophylaxis alone as an independent risk factor.

You also considered whether it was possible that the combination of the antibiotic regimen and the thromboprophylaxis regimen together could have been a confounding factor?

A I think, if I can -- I'm not sure what you're asking, if you're asking is -- was I considering whether there was some form of, quote, "interaction

between the two."

Here my and/or referred to antibiotic use or to thromboprophylaxis and not to particular combinations of the possibilities of those two.

Q You understand that in the McGovern study during the Bair Hugger only period, there were two different antibiotic protocols --

A Yes.

Q -- used versus one in the HotDog period; right?

A I understand that, yes.

Q And you understand in the Bair Hugger period, there were two different thromboprophylaxis protocols used; and in the HotDog period, there was only one --

A Correct.

Q -- thromboprophylaxis?

Prior to your writing your report, were you aware that there was a period in the Bair Hugger only time period that was reported by McGovern, et al., where the Bair Hugger patients, the Bair Hugger cohort, had the same antibiotics and thromboprophylaxis as was used for all of the HotDog patients?

A I'm sorry. Can you say that again.

Q Prior to rendering your opinion and writing

your report, were you aware that there was a period of time during the HotDog or -- strike that.

Were you aware that there was a period of time during the Bair Hugger only time period where the identical antibiotic and thromboprophylaxis regimen was used as was used for the entire Bair -- HotDog only period?

A I think -- I think I was. And of course since then, I've seen the Holford report, which goes into this in great detail and lays out the diagram.

So I have a little trouble separating the pre March 30 with post. But I looked carefully at what was in the different intervals.

Oh, did -- I lost -- thanks. I'm sorry. Oops. Give me a moment to repair, please. I was sitting on it. Okay. Okay.

Q Do you know Professor Holford?

A I know who he is. I think we probably met. I'm familiar with his work, yes.

Q You cited it on occasions?

A Yes.

Q Do you -- do you respect him as an authority in -- in the field of biostatistics?

A I think he's well-known and a well-regarded figure, yes.

Q When did you read his report?

A I'm sorry. You're referring to his --

Q Well, I may have misunderstood. I thought you said you -- I'm not -- I -- let's clarify.

MR. GORDON: I'm going to mark this as Exhibit 3.

(The aforementioned document was marked Exhibit 3 for identification by the reporter.)

BY MR. GORDON:

Q I'll represent to you that this is the expert report in the exhibits that were submitted by Professor Holford on behalf of the defendants in this multidistrict litigation.

Have you seen this before?

A Yes, I have.

Q And when did you first see this?

A Perhaps a month and a half ago. Again just -- just guessing.

Q Okay. And so I want to be -- before when we talked about things you have seen since you rendered your opinion, you mentioned the Augustine publication.

Then -- I -- I thought you had mentioned this, but I want to clarify that. And I thought you also mentioned a printout of a data set.

What -- are there any other things that you -- you reviewed relating to the Bair Hugger that -- since your -- since you rendered your opinion?

A You mean that are in addition to?

Q In addition to the Augustine article, you mentioned the -- the printout of a data set and the Holford report.

A Oh, Dr. Borak's report.

Q Okay. Any -- any other of our -- of defendant's expert reports?

A I don't think so.

Q Did you read Professor Wenzel's report?

A Professor --

Q Richard Wenzel.

A I did see his report.

Q When you say -- I want to -- I mean, maybe it's semantics.

When you say you saw it, does that -- you mean you -- you read it or --

A It was provided to me, and I read it, yes.

Q You read it cover to cover?

A I read it cover to cover but not -- not nearly so carefully as the Holford and Borak reports.

Q Okay. And which also makes me -- leads me to a question about the -- your reliance materials,

Exhibit C, in your report.

When you list these -- these -- all of these items, are these things that you actually sat down and read from beginning to end or --

A No.

Q Okay.

A Actually, I scanned many of them. And some of them, I read beginning to end.

Q Can you tell me, starting with the deposition transcripts, did you read any of those deposition transcripts from beginning to end?

A I did. Now, as to which ones, it would be -- it really would be a challenge because a lot of -- you know, a lot of materials are included here. And I, frankly, would have a hard time sort of saying I read that much of this one or that much of that one. It would be very difficult.

Q Did you read -- did you read either of the days of Mark Albrecht's testimony from beginning to end?

A I definitely read much of his testimony. Whether I read it beginning to end specifically, I just couldn't say sitting here today.

Q Would you have read much of it prior to your rendering your opinion on March 30?

A I probably did. I looked at these as they came in. I can't comment on the specific time.
Q Have you reviewed any of the materials that are listed on Exhibit C since March 30 prior to today?
A No.
Q So whatever -- whatever you reviewed about Albrecht -- or --
Whatever part of Albrecht you've reviewed, you reviewed it prior to rendering your opinion?
A Yes. And I may have looked -- again, you know, I think I've gone back and looked at some of the McGovern bits and -- bits and pieces. But primarily most -- most of this was read before March 30.
Q Do you remember a discussion in the Albrecht deposition that concerned the -- the issue that we were discussing a few moments ago, the fact that there was a time period within the Bair Hugger study when antibiotics and thromboprophylaxis were the same as used in the HotDog period?
A I can't say specifically.
Q So would you agree just as a general proposition if you were interested in seeing if antibiotics and thromboprophylaxis could have been a confounder as between Bair Hugger and HotDog, the best way to eliminate the possibility of the -- of them --

those two things being a confounder would be to compare a time period within the Bair Hugger time period where the same antibiotics and thromboprophylaxis -- -prophylaxis was used as was used in the Bair Hugger era and the HotDog period?
A That -- that would be one approach. But it would come at the price of reducing the size of the data available.
Q Prior to your rendering your opinion, did you -- did you try to do that?
A As I said already, I did not do any primary data analysis.
Q Do you recall -- well, have you, as you sit here today -- I mean, when you said that there would be a price to pay, I'm assuming that you somehow have learned that there was a time period and have some sense as to how -- what that time period was length-wise or -- or number of patients-wise.
Right?
A There were -- there were some months. And I -- perhaps it's Holford who assumes that analysis. I don't recall specifically. But such an analysis was done. And, actually, I see that on page 6.
Q So page 6 of Holford's report?
A Page 6 of Holford's, correct.

Q When you read that, did you go back and look at any of the source materials upon which he based that analysis?
A I'm sorry. But I've already said I did not do any primary data analysis.
Q Okay. Do you remember reading testimony of Mark Albrecht where he testified that the -- there would be no significant difference in the infection rate in the period -- the five-month period within the Bair Hugger study compared to the seven-month period of the HotDog study when antibiotics and thromboprophylaxis were identical? You do remember that?
A I -- I don't remember the specific details of Albrecht's testimony.
Q Just generally do you remember any testimony of Mr. Albrecht that suggested or -- or agreed that if you eliminated antibiotics with thromboprophylaxis, by comparing the identical regimens there was no statistically significant difference?
A I -- you know, again, I did not review the Albrecht materials recently enough to give an answer to that question.
Q Okay. Well, when you read Dr. Holford's analysis where he demonstrated that the -- that the

infection rates were virtually identical, the relative risk of one, did that -- did you look at that and say, "Gee, Holford is just wrong"?
A Well, I guess -- I guess a couple of comments.
I mean, one -- one would be that clearly the comparison would have a very wide confidence interval around it, whatever they -- whatever the estimate was, which was what I said. That's the price of stratifying the data and taking only a -- a -- a portion of it.
And, you know, there's still this a priori question about the case that can be made for confounding by the -- by the antibiotic and thromboprophylaxis regimens.
Q What would you consider a wide confidence interval?
A I -- again, this is like other -- other terms that I use. I -- I will -- I will just say I don't have rules.
But with three events and four events in two groups, I'm sure it calculated and provided the confidence intervals. It would be substantial. It's wide. Any -- any word you want. But they would be -- it -- it would cover a broad interval.

Q What was the -- the recorded confidence interval for the relative risk in the McGovern paper which you would consider to be a wide confidence interval?

A Again, I'm going to refresh my memory --

Q Yeah.

A -- as to what it was.

(Witness reviewing document.)

THE WITNESS: 1.2 to 12.5. I certainly would not describe it as narrow.

BY MR. GORDON:

Q Okay. Well, do you characterize that as a wide confidence interval?

A I -- again, I don't have particular rules. I mean, I think it's -- it's a substantial interval covered by 1.2 to 12.5.

Q And the fact that it didn't dip below one, that was important to you?

A Well, that -- that indicates that the .05 level is actually this, yeah.

Q Now, we were -- I'm sorry. I got diverted. We were talking about strength and association and the impact that that has on whether you could conclude that confounding was unlikely.

And you said that 3.8 moderately strong

strength of association, that allowed you to conclude that such confounding was not only unlikely but not supported by the evidence.

What I want to know is, Numerically how low would it have to go before you can say "You know, that's" -- "that's in that" -- "in that zone where I'm not so sure the odds ratio for relative risk in and of itself is particularly useful one way or the other in assessing whether there's a" -- "there's an impact of confounding"?

A Well, there's no -- I can't say there's a specific quantitative rule or principle. It would really depend on the strength or the potential confounders as risk factors themselves.

Q You were critical in your report and critical of many publications of the efforts of the tobacco industry to discredit the various observational studies that initially linked to -- cigarette smoking to cancer; correct?

A I've commented on that, correct.

Q And -- and specific -- specifically one of your criticisms is the tobacco industry tried to create doubt by suggesting there may be unknown confounders that -- that are causing the difference in the -- the odds ratios that are coming out in the

various observational studies; right?

A I've written that kind of statement, correct.

Q And the studies upon which the initial conclusions about cigarette smoking and lung cancer were drawn in the surgeon general's report, those were based on, among other things, animal studies and other things, twenty-nine different observational studies; right?

A I'm sorry. Which report are you referring to?

Q The 1964 surgeon general's report.

A That may be the number. There were seven or nine observation -- cohort studies and another twenty-something case studies.

Q And with respect to men and lung cancer in moderate to heavy smokers, every single one of them had a strength association with at least nine. One was high -- I believe it was somewhat higher than twenty and thirty.

Right?

A There were very strong associations, that is true.

Q Those were very strong associations; right?

A Strong. Yes, very strong.

Q Much stronger than 3.8; right?

A 12 is bigger than 3.8.

Q Well, in terms of taking those -- those very high odds ratios across literally dozens of studies and saying "You know what, those" -- "in three different" -- "in three different countries, those" -- "those odds ratios are so strong and so consistent, that that pretty much excludes the possibility of" -- "of some unknown confounder that the tobacco industry was trying to suggest might be in play," that makes perfect epidemiological sense, doesn't it?

A It just makes perfect common sense, but yes.

Q But taking one observational study that concludes there's a 3.8 odds ratio and concluding that that odds -- that that odds ratio was sufficient to -- to exclude the possibility of a confounder -- one or more confounders, that -- that doesn't stand on -- in the same solid scientific domain as we were just talking about with respect to cigarette and lung cancer studies; right?

MS. CONLIN: Objection as to form.

THE WITNESS: If I can comment. The tobacco situation is unique in terms of the strength of association of smoking with lung cancer.

The matter of confounding is something

that's looked at study by study by study. First off, confounding is the property of a particular data set because of the potential confounders that are there.

So my -- my comment is in reference to this particular study. It's the one at hand.

BY MR. GORDON:

Q Well, would you agree with me that -- that particularly medical science is -- is replete with individual observational studies that showed some strong association that was later demonstrated through robust prospective randomized clinical trials and multiple epidemiological studies to have been erroneous?

A Not sure "erroneous" is the right word. The question is, Are there false positive, if you will, findings that don't hold up on replication? The answer is yes.

Q You are familiar with the Nurses' Health Study; right?

A I am.

Q Were there a number of -- actually, well over a thousand published papers that went back and tried to find associations between various things and various outcomes based on the data compiled in the

Nurses' Health Study; right?

A There were many papers in the Nurses' Health Study.

Q Have you ever seen any analysis of how initial findings from the Nurses' Health Study held up under subsequent scrutiny with additional studies?

A I -- (coughing.) Excuse me. I do recall seeing -- a paper that I saw in the last three or four or five years.

Q And what's your recollection about the conclusions of that, the paper that you saw? Did those initial findings in the various papers by and large hold up to further scrutiny when they were replicated or subjected to more robust clinical trials?

A So I don't remember all the details, again, of this paper. I think the general intent of the paper was to take some of the associations observed in the Nurses' Health Study and follow up and look at what was observed in clinical trials.

And I know -- I know that the general message was that some of them had not held up. And I don't remember the quantitative details of that paper.

Q There was quite a few, wasn't there? It wasn't just a couple -- a couple here and there didn't

hold up. But overall they -- they -- everyone --

A I just would have to see the paper again to comment on that.

Q Well, let's -- let's talk about one specific finding, then, that I think you're pretty familiar with. The -- based on the data from the Nurses' Health Study, there was a pretty strong consensus in the medical community that hormone replacement therapy was a good thing for postmenopausal -- for postmenopausal women; right?

A That's a question that I wouldn't answer simply yes or no. It had some adverse effects and some potentially beneficial effects.

MR. GORDON: I'm going to show you what I've marked as Samet Exhibit 4. I will represent to you that this is a partial printout of the 2004 surgeon general's report on consequences of smoking, at least a partial. I didn't want to destroy a forest of trees.

(The aforementioned document was marked Exhibit 4 for identification by the reporter.)

BY MR. GORDON:

Q But you were -- you were involved in this report, were you not?

A I was the senior scientific editor.

Q And in particular, the -- the section that is the -- in the introduction in Chapter 1 on approach to causal inference, you -- you would have had a significant involvement in the drafting of that section; correct?

A I was one of the authors of it.

Q Okay. Now, if you -- page -- turn to page 19 --

(Witness turning to page.)

BY MR. GORDON:

Q -- and the discussion of judgment in causal inference. You and your co-authors wrote -- this is in the second full paragraph on the right-hand side of the page. (Reading):

"Properly designed studies provide a scientific basis for inferring what the outcome of the counter-factual state would be, and permit related uncertain" -- "uncertainty to be properly quantified."

Right?

A That's what it says.

Q And you certainly agree with that today;

right?
A Yes, I do.
Q You go on to say (reading):
"But in observational studies of humans, scientists must try to infer what the outcome would be in a counterfactual state by studying another group of persons who, at least on average, are substantively different in only one relevant variable, the exposure under study."
Is -- you -- that's something you still agree with; right?
A I do.
Q Now, you discuss the challenges of doing randomized assignments under certain circumstances.
And at the bottom, you start to say (reading):
"In the absence of a randomized assignment of exposure, two groups may differ on average in more factors than just the variable of interest. If these other factors affect outcome, then their effects

can combine with the causal effect of the factor of interest, biasing the measured effect of that factor. These ancillary causes are called confounders."
Right?
A Correct.
Q You certainly still agree with that?
A I do.
Q You go on to say (reading):
"As an example of a confound" -- "An example of a confounding factor might be a characteristic associated both with taking a medication and cardiovascular risk, which appears to be the current situation with hormone replacement therapy (HRT) in women. The observational studies showed a clearer cardiovascular benefit from HRT than did a large randomized trial, suggesting that there may be some cardioprotective characteristics or behaviors of women who voluntarily

take HRT that are at least partly responsible for the apparent benefit of HRT in the observational studies."
Citing Hulley and Blumenthal.
Continuing (reading):
"In fact, the results of the Women's Health Initiative Trial of HRT showed increased risk for cardiovascular disease incidence in women randomized to HRT."
Citing Pradhan. (Reading):
"Confounding by cardioprotective characteristics associated with taking HRT may have obscured these unanticipated con-" -- "this unanticipated consequence of HRT in the observational studies."
Could you translate that for those of us who aren't epidemiologists what you were talking about here with respect to hormone replacement theory -- therapy and the observational studies and the cardioprotective characteristics.
A Sorry. Do you want a translation --

Q Yes.
A -- or a lecture or --
Q Well --
A I mean --
Q I'm not an epidemiologist, but correct me if I'm wrong. The observational studies based on a lot of data, very big numbers of participants in high power, in the nurses' study showed that HRT, hormone replacement therapy, had clear cardiovascular benefits to when -- when it was -- a randomized clinical trial was done with a broader cohort of -- of women than just nurses, not only did it not -- did those -- did that trial and other subsequent trials not show a benefit, it showed that it actually increased the risk of cardiovascular disease; right?
A That's the results of the WHI, the Women's Health Initiative, correct.
Q Well, and when you were talking about confounding by cardioprotective characteristics, you were talking about the fact that you were looking at a group that are -- whoever was looking at the nurses' study was looking a group that had characteristics that were not translatable to -- to a -- to a broader cross-section of -- of all women; right?
A Sorry. Maybe I'll try to say this like it

is.

The issue here was that women in the observational studies who ended up on hormone replacement therapy differed in some ways. Their report for cardiovascular risk was -- who did not.

It was not a matter of the general legibility of the nurses, but the difference within the nurses or some other studies at the time between those on HRT who were not assigned randomly but who took it versus those who did not.

Q Well, I'm not sure I understand, and that's my problem.

The initial observational studies showed a clear benefit from HRT; right?

A For cardiovascular disease.

Q For cardiovascular, correct.

A Right.

Q But in subsequent randomized clinical trials, not only was there not that, but there was a detriment -- a statistically significant detriment in cardiovascular disease; right?

A There was an increased risk for cardiovascular events, yes.

Q Would you agree that there -- there -- that's not an isolated example in the history of medicine

where -- where an initial approach to some therapeutic intervention was perceived as being either positive or -- or negative based on one or more observational studies that on attempts of replication and/or more focused randomized clinical trials did not prove to be accurate?

A I think I said before that not all observational studies with findings that purport to show associations are replicated.

Q Wouldn't you agree that a single observational study is without replication generally a weak basis for drawing definitive causal conclusions?

A I think a -- the observational study, the findings need to be interpreted in light of what is known about the association with regard to coherent plausibility and -- and so on.

Q Well, one of the criteria that suggested that was used by the surgeon general's report and that you yourself discuss is consistency; right?

A Yes.

Q And that's important because one study may not have gotten it right. But it -- the more studies you have that came -- that come to the same conclusion, the more likely it is that the conclusion is correct and not an outlier result of some bias, a

result of some unaccounted for confounder, or something like that; right?

A Well, having multiple studies with similar findings adds to the confidence in -- in the findings, correct.

Q Okay. Well, you go on to say in this 2004 report that (reading):

"If confounders are recognized and their effects measured, these effects can often be statistically minimized or removed by the analysis of a study. However, if a confounder is poorly measured, or its effects poorly characterized, then its effects cannot be controlled for in the analysis phase of a study, resulting in a causal effect that is distorted or confounded by the unwanted factor. The most extreme version of this phenomenon occurs with unmeasured confounding, causal factors that are not measured at all and whose effects are therefore not controllable, which can result in

biased estimates and underestimates of uncertainty, because standard analyses implicitly assume an absence of confounding from all unmeasured factors."

Did I read that right?

A You did.

Q And you still agree with that; right?

A Yes.

Q And the only potential confounders that you even considered for the McGovern study in rendering your opinion were antibiotics and thromboprophylaxis?

A Well, again, as I said, with this interrupted time series design -- excuse me -- design, there would have to be other factors that were linked to a time period that fit the definition of confounders. And I just don't have any basis for suggesting what they might be.

Q Did you do anything to try and determine if there were potential confounders --

A I --

Q -- besides the two that you looked at?

A Again, these -- my -- my judgments are based on the information and the materials used.

Q And you didn't do the analysis where you

isolated the Bair Hugger period where the antibiotics and the thromboprophylaxis were the same as in the HotDog period.

But do you have any reason today to disagree with Professor Holford, Mr. Albrecht, Dr. Reed, and Dr. McGovern that when you compare those two time periods completely eliminating the potential for thromboprophylaxis and antibiotics to be different, there is no difference in the rate of infection?

MS. CONLIN: Objection; it assumes facts not in evidence.

THE WITNESS: Again, I think I commented on this.

One is I'm not sure on an observational basis why these two factors would be kind of considered as independent risk factors.

And, second, yes, I have seen the Holford analysis and understand what is there.

BY MR. GORDON:

Q Let's talk about the antibiotics.

Do you recall what the --

MS. CONLIN: We're at like 1:15. So.

MR. GORDON: Do you want to break now?

MS. CONLIN: No, it's up to you. But I know he wants to eat at some point. So I don't

want you to get into --

THE WITNESS: Actually, a break time would be good.

MS. CONLIN: Do you mind?

MR. GORDON: That's fine.

THE VIDEOGRAPHER: The time is 1:15 p.m. We are off the record.

(At the hour of 1:15 p.m., a luncheon recess was taken; the deposition resumed at 1:50 p.m.)

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LOS ANGELES, CALIFORNIA; TUESDAY, JULY 11, 2017

1:50 P.M.

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JONATHAN SAMET, M.D.,

having been previously administered an oath in accordance with CCP 2094, was examined and testified as follows:

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EXAMINATION (Resumed)

THE VIDEOGRAPHER: We are back on the record. The time is 1:50 p.m.

BY MR. GORDON:

Q Dr. Samet, I'd like to talk about antibiotics.

There -- do you recall there where two different antibiotic protocols during the McGovern interrupted time series that we were discussing; right?

A Correct. Yes.

Q Do you remember what they were?

A Gentamicin and gentamicin plus teicoplanin.

Q Okay. And the HotDog only cohort received the gentamicin-teicoplanin combination for all the -- the HotDog cohort period; right?

A Yes.
Q And with the Bair Hugger period, some received gentamicin only and some received gentamicin plus teicoplanin; right?
A Correct.
Q Now there's no antibiotic that is universally effective against every bacteria; right?
A In general, that's true, yes.
Q Do you know of any antibiotic that you would describe as effective against all bacteria?
A Not at this point, no.
Q Okay. What is gentamicin effective against?
A Primarily gram-negative organisms.
Q Is it effective against -- looking back in the 2008-2010 time frame, was -- was gentamicin effective against Staph Aureus?
A It would not be a first line drug for Staph Aureus.
Q How about if it was negative to staph?
A I actually, don't recall the spectrum of gentamicin for such staph. But it's certainly not a -- a drug that comes to mind for a gram-positive organism.
Q What's -- what is teicoplanin effective against?

A It's primarily directed to gram-positives.
Q And somebody did a study and compared one cohort that had only gentamicin and another cohort that only had -- only had teicoplanin.
And somebody in the gentamicin -- or several people in the gentamicin group developed a gram-positive infection. And few or none developed -- in the teicoplanin group developed a gram-positive infection.
And you just looked at gram-positive infections and did the odds ratio, and you found that if you just had gentamicin, you had a much, much, much higher odds -- relative risk or attributable risk of getting a gram-positive infection than if you -- than if you were being treated with gen- -- teicoplanin.
That's -- that's a hypothetical that I'm going to set up for you. Okay?
A Okay.
Q In that hypothetical, no matter how high the relative risk or the attributable risk that you compared it to, you wouldn't opine that gentamicin caused the gram-positive infection in people who received gentamicin only, would you?
MS. CONLIN: Objection; it calls for speculation.

You may answer.
THE WITNESS: I -- I would not consider an antibiotic as a cause for infection, if that's the question.
BY MR. GORDON:
Q Well, but if gentamicin doesn't treat gram-positives and somebody getting only gentamicin gets a gram-positive infection, even if the relative risk is a hundred versus teicoplanin, you wouldn't say that there -- that gentamicin caused it; right?
A No, that's correct.
Q You -- you --
A That's how -- that's how I answered it. Correct.
Q You would say -- you would say in terms of relative efficacy, gentamicin was relatively much less effective against gram-positives than teicoplanin; right?
A Or teicoplanin plus gentamicin, which is the comparison you offered in your hypothetical.
Q Okay. And the only data upon which you base your opinion is a head-to-head comparison between two different warming modalities; right?
A Sorry?
MS. CONLIN: Objection --

BY MR. GORDON:
Q The only difference -- the only study -- strike that.
The only data on which you base your opinion is just a head-to-head comparison between two different types of warming modalities forced-air warming and convective [sic] blankets; correct?
MS. CONLIN: Objection as to --
BY MR. GORDON:
Q Conductive blankets.
A I'm sorry. I think my expert report covers a lot more ground than a single study.
Q Okay. Well, there are -- are there any data upon which you rely that compared Bair Hugger to nothing?
A The -- the observational data that I examined was the McGovern study in my March 30 report.
Q And that compares one warming modality to another; right?
A That's correct.
Q Would you agree that at most, even if ultimately it's determined that that study is -- is valid and the conclusions were not confounded by anything, it really is forced-air warming versus the -- the blanket, you can't conclude that the Bair

Hugger is causing infections. It's just not as effective as the other warming device in preventing them; right?

MS. CONLIN: Objection as to form.

THE WITNESS: I think that's a rather different interpretation of the evidence than I have offered.

BY MR. GORDON:

Q I agree.

I'm asking you, If you're comparing two different modalities that are therapeutic intervention, the -- the -- among the purposes of which includes infection reduction, if one is more effective in reducing infections than the other, you can't conclude that the one that isn't quite as effective is causing the infection; right?

A Well --

MS. CONLIN: Objection as to --

THE WITNESS: -- again, my -- my interpretation of the findings in the McGovern study is based on the other evidence I cited in the report, which had to do with the other consequences of having the Bair Hugger in the operating room.

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BY MR. GORDON:

Q Well, is there any reason why those consequences would differ from the Wansbeck General Hospital in Northumbria to all other hospitals in England?

A Sorry. I just don't understand the question.

Q Can you think of any reason why the one -- the way the Bair Hugger performs in the Wansbeck General Hospital would be different than the way the Bair Hugger performs in other hospitals throughout England?

A I don't really have a basis for answering the question.

I mean, if your question is the generalizability from one hospital to another in England a priori, I don't have sufficient understanding of how hospitals may -- might -- might differ across England, which I think is what you base the question. I assume that operating rooms are to an extent comparable and perhaps different in some ways.

Q When you read Dr. Holford's report, did you read his analysis of the infection rates, reporting of the McGovern study at Wansbeck General Hospital as how -- as how they compare to reported rates from hospitals throughout the -- the English National

Health system?

A I saw the distribution of infection rates that Dr. Holford had in his report.

Q Did you do any independent research to see if the -- the numbers that Professor Holford used and calculated were -- were accurate?

A I don't know about accurate. I think one -- one question is whether the numbers were generated in different ways.

At least per McGovern, an active surveillance system was implemented in 2008 at Wansbeck. And I'm not sure that the actual -- of the deep joint infections was comparable at the other hospitals that Holford looked at.

Q Did you do any research to see if it was or wasn't?

A I'm not sure what research I could have -- could have done. I -- I do know that there was an effort -- an active effort at Wansbeck to address infections, and they implemented a two-person proactive -- active surveillance system.

Q Do you know anything about the policies and requirements of the National Health Service in England for hospitals to report infections after knee and hip surgeries?

A My reading of what is included in these materials was that it was previously once a quarter and that Wansbeck implemented this active surveillance system in 2008. Now, what other hospitals might have done in that regard, I don't know.

Q So if -- whether other hospitals that used a Bair Hugger reported four quarters throughout this period of time or not, you have no idea; is that correct?

A Well, I think the question is whether they had similarly proactive surveillance. And that, I can't answer.

Q Well, one of the reasons that people first started suspecting that there might be a linkage between cigarette smoking and cancer was that prior to the beginning of the twentieth century the rate of lung cancer was fairly low, and starting somewhere in the early part of the twentieth century it started to rise very dramatically; right?

A Well --

Q I know I'm not using epidemiologic terms.

A -- to be -- to be fair and accurate, there were reports from clinicians of rising lung cancer rates that would cause mortality. That wasn't really tracked in the United States until the thirties.

Q At some point along the way, somebody got the idea that, hey, there seems -- there seems to be a lot more lung cancer than there used to be; right?
A A number of people came to that conclusion.
Q And it seemed to be coincident with the rise in popularity of cigarettes; right?
A That was one of the hypotheses.
Q And that's a hypothesis that ultimately proved to be the case; right?
A Correct.
Q Obviously, that's not an epidemiological study. But looking at big numbers like that, gee, there's been a steep rise in -- in lung cancer. There's been a steep rise in cigarette usage. Maybe there's a linkage.
That -- that's at least one sort of check on the -- the validity and the reliability of observational studies; right?
A I'm not sure it's a check. It might be part of the evidence considered under coherence of what is relevant.
Q Okay. So would you -- would you consider that to be part of coherence? Right?
A Yes.
Q Okay. Well, if the Bair Hugger has an

attributable risk of 73 percent, wouldn't you expect that hospitals using the Bair Hugger would have higher rates of infection than the Wansbeck Hospital had after they switched to the Bair Hugger -- to the HotDog?
A I think that's a -- a -- a question that -- I actually in my expert report talk about that kind of investigation and the potential limitations of doing both, what would be highlights with an ecological study of the hospital where the unit of analysis and that kind of comparison was -- was made. I'm not sure it's a very, if you will, sensitive design.
Q Would you -- would -- would a demonstration that hospitals doing active surveillance reporting four quarters that used the Bair Hugger have consistently lower rate of deep joint infections than Wansbeck General achieved after it switched to Hot -- to HotDog -- that that fact alone is something that would at least give you some pause as to whether the -- the findings of McGovern have any transferability outside of the Wansbeck circumstances?
A So in this hypothetical, I -- I think the generalizability results from Wansbeck would depend on -- other hospitals in England would depend on whether the surveillance was the same.

And -- you know, and I don't know whether there's something particular about Wansbeck, if more difficult cases end up there or not, so...
But I -- I think if your question is in this hypothetical -- I just couldn't go much further in interpreting what you found, what you suggested.
Q Well, you've -- you've concluded that the Bair Hugger is a substantial contributing cause because it has a 73 percent attributable risk based on the 3.8 relative risk found in McGovern; right?
A Correct.
Q And you're opining for all these cases, more than 2,000 now in the United States where people had their surgeries performed in dozens -- hundreds of different hospitals throughout the United States.
Your -- your opinion is that you could take that finding in Wansbeck and transfer it to all these hospitals throughout the United States and say, yep, it's the Bair Hugger 73 percent of the time.
A Well, I -- I think in that -- in that regard, it's useful. But there's now a second report that is from the United States hospitals that essentially has a very similar quantitative estimate of the risk of the Bair Hugger.
Q Are you aware that the -- well, strike that.

Did you take a look at the individual hospital numbers in that Augustine study that you --
A I'm -- I'm aware there are variations in the risk estimates across the three hospitals, yes.
Q And you're aware that one hospital dominates and accounts for more than half of the cases, and that without that hospital in there, there would be no significant results?
A You know, again, I'm aware there's heterogeneity by these hosp- -- three hospitals.
Q Are you aware that that hospital has publicly said there are many factors that resulted in our reduction in infection rates, and we do not agree that the switch from Bair Hugger to HotDog was the reason for the decline in infection rates?
MS. CONLIN: Objection; it assumes facts not in evidence.
THE WITNESS: Yeah, I'm not -- I'm not aware of what's been said in that regard.
BY MR. GORDON:
Q Are you aware that that hospital has -- has disavowed Scott Augustine's use of data he obtained from them?
A I -- I have no such knowledge.
Q Would it have any impact in your -- your

consideration of the reliability of Scott Augustine's --

A I think --

Q -- publication?

A -- I have some deeper understanding of why the hospital made that statement.

Q By the way, when you -- when you submitted your various papers to publications, are you generally required to provide the publication with two names of potential reviewers?

A Generally, no.

Q Have you -- are you aware of any publication that you've ever submitted to that required you to submit the names of two potential reviewers?

A I -- I couldn't answer that. I've submitted to so many journals. Some -- sometimes they may ask for appropriate reviewers required. I've just -- I don't think I've had that experience. But I can't attest to the hundreds of journals that I probably submitted to at this point in my career.

Q Does that strike you as kind of an unusual requirement, to require an author to identify reviewers?

A In my experience, it's not -- it's not that frequent for me, in my view.

Q In -- in your experience, typically how long does it take to -- for the review process to work?

A It's highly variable.

Q What's -- what's the confidence interval? What's the shortest period you've experienced and the longest period?

A I'm sorry. I -- I wish -- I wish I could answer. I will say -- let me just say that, you know, on average, it's a couple months from submission to getting back, you know, initial comments from an editor.

Q How about from initial submission to actual acceptance for publication?

A It depends on what's asked for in the revisions. I mean, I certainly had papers that have taken months to do revisions and reanalyses and other things. And sometimes it's very quick. It really depends on what's called for.

Q When you say "quick," how -- how quick is quick? What's the --

A Oh, if it's minor revisions, it might be sent back within a several weeks and have an accepted manuscript.

Q When you said you noticed the -- that there were two different dates in the Augustine paper when

it was accepted for publication -- or when it was submitted and when it was accepted, did you count the number of days in between?

A No.

Q Would it surprise you if I -- if you were to find out there were forty days in between submission and acceptance and those forty days included Christmas and New Year's?

A I'm not sure I'm surprised. It's on the -- on the briefer end of the time -- time duration I discussed.

Q That would be pretty quick for -- for the conscientious peer review process to work its way through in your experience; right?

A Oh, I -- I think that's highly variable. And I will say it's a brief -- brief manuscript with relatively, you know, limited presentation of data. So perhaps it was done quickly.

Q Let's go back to antibiotics. You -- you said that gentamicin was not the first line drug for Staph Aureus.

What did -- what did you mean by that?

A Well, again, that typically Staph Aureus would be treated with other types of antibiotics besides gentamicin, which -- which -- in my

experience, which is now admittedly in the past, was used for gram-negative infections primarily.

Q Okay. When you looked at -- strike that.

The McGovern analysis is based on aggregate infection data; right? Total numbers of infections of any type?

A Yes.

Q Nowhere in the McGovern paper itself is there any breakdown in the types of infections that were occurring from the two different periods; right?

A That's correct from my recollection, yes.

Q But you had available to you at least the specific bacterial infections that all which were listed in Exhibit 16 to the McGovern deposition, which you did list as one of the things you reviewed; right?

A I don't recall specifically that type of infection was included in what I've seen as the primary data, so I can't comment on that.

Q Did -- did you look at the types of infections?

A No.

Q Were you curious?

A Was I curious about -- I'm not sure I understood that the data were there.

Q Okay. So you -- you concluded the -- the

change in antibiotics had no impact on the overall infection; right? That was one of the -- one of the conclusions; right?

A I concluded that it was not a confounding factor, correct.

Q How many Staph Aureus cases were there in the HotDog cohort?

A I said I've not looked specifically at the breakdown of infections by organisms.

Q Would it surprise you to learn that there were zero Staph Aureus infections in the HotDog only cohort?

A I don't know about surprise. I take that as what it is. I mean --

Q Well, would it surprise you to learn that almost a third of the infections in the Bair Hugger only cohort were Staph Aureus?

A Really the same answer.

Q Well, would you agree that if you look at the overall infection rates when they stayed the same, that doesn't tell you if the antibiotics which is a confounder with respect to specific infections like Staph Aureus?

MS. CONLIN: Objection as to form.

THE WITNESS: Sorry. Can -- can you

repeat.

BY MR. GORDON:

Q If you're using an -- a drug like gentamicin that is ineffective against Staph Aureus and during the time that you're using gentamicin only you have a few Staph Aureus cases and after you switch to adding teicoplanin, which is effective against Staph Aureus, your -- and the number of Staph Aureus cases goes down -- in fact, in the case of the HotDog only period, it drops to zero -- would you agree that the question of whether the antibiotic change had -- it was a confounder while it may not reflect -- be reflected in the overall numbers, it certainly is worth looking into whether it might have been a confounder with respect to Staph Aureus infections?

A Well, I -- I would be surprised if the data were -- were robust enough given the sample size of the infections to explore specific infectious organisms.

But I understand the genesis of the question. But I think it would be, with the data at hand, very hard to address.

Q Well, so if an intervention is made for the purpose of a specific type of organism and there is a decline in those organisms, but other organisms don't

decline or maybe even go higher, your analysis of whether that intervention with respect to that specific organism has any confounding would be that no, because the -- you know, the overall rate is the same, forget about what it -- what it did -- for what it was supposed to do, that's -- your view is that that wasn't -- that that's not a confounder?

A No, I -- I didn't -- I didn't say that. I -- I think it's a little hard to have -- have this discussion without actually having a better understanding of the rate of staph infection in the Bair Hugger period and in the conductive warming period.

Q Which you didn't analyze?

A I said I did not.

Q Did you see that Dr. Wenzel did when you read his report?

A I don't recall specifically Wenzel's report, but...

Q Do you recall reading in Dr. Reed's deposition that the Wansbeck Hospital or the Family Trust instituted screening for methicillin-susceptible Staph Aureus in January 2010?

A I recall that they implemented a program, I think, with nasal spray and so on.

Q Not just screening. It was also decolonization of positive --

A Correct.

Q -- strains?

MS. CONLIN: Objection; it assumes facts not in evidence.

BY MR. GORDON:

Q Well, do you recall reading Dr. Reed's testimony where he said that --

A Well, I -- I do. I do recall the story.

Q Did you look at the number of Staph -- Staph Aureus cases before and after MRSA screening was implemented?

A No, I did not.

Q And again you got Staph Aureus happening during the Bair Hugger only period when it was gentamicin and no MRSA screening. And in the HotDog period you have no Staph Aureus after this had been implemented and the addition teicoplanin and MRSA screening.

And your opinion is that that doesn't matter because the overall rates, that's all that matters?

A That's not my opinion. I'm not sure how you got to that.

Q Well, if the number of Staph Aureus cases in

the HotDog only period was zero, all of the -- well, strike that.

If the vast majority of the Staph Aureus cases that occurred in the HotDog period occurred prior to the time that both teicoplanin and MRSA screening was implemented and no Staph Aureus cases occurred during the HotDog period after the MRSA screening and teicoplanin were implemented, would you still be able to rule out teicoplanin and MRSA screening as having any confounding impact on infection rates?

A Well, I think you said the key thing, which is infection rates in the observation period for conductive warming is shorter than that for forced-air warming.

I just would have to look at the data to see what the expectation was coming from the gentamicin as to how many cases you might expect. There's a small numbers issue here.

Q If -- if somebody did an observational study and compared smokers and nonsmokers and looked at all cancers as an end point, it turns out that, gee, in the smoker group there's a much higher incidence of lung cancer, but in the nonsmoker group there's several incidents of melanoma, brain cancer, perhaps

some other things that I think you'd agree were not -- have never been associated with cigarette smoking, but the overall incidence of cancer was pretty comparable, would you think that observational study would be a valid study for saying, hey, smoking doesn't cause cancer?

A I'm not sure -- sorry. I just -- if I can restate what I think I heard you say. There's a study of smokers and nonsmokers.

And in the smokers, there's a large number of lung cancer cases observed?

Q If you just look at lung cancer, there's an increased -- a substantial increased relative risk compared to the nonsmokers.

A Uh-huh.

Q But if you look at all cancers, because the nonsmoker group in my hypothetical has melanomas and brain cancers, the overall incidence of cancer rate renders it not -- the difference not statistically significant, would you conclude from that that smoking doesn't cause cancer?

A Again, I'm -- this is a hypothetical hypothetical. And I'm -- if you're saying that an outcome is a composite and it includes some cancer specifically related to smoking among others -- I

think that's what I heard.

Q Yeah. An aggregate. All cancers.

A Well, I -- I mean, again, I -- I will say if the analogy is to looking at all infections, I don't think there's an organism-specific question here related to Bair Hugger that it only causes one kind of bacterial infection.

Q But you decided there's no organism-specific question related to any of the other interventions that -- that the Wansbeck Hospital took prior to the switch to HotDog; right?

A I'm sorry. Can you repeat that again.

Q You -- you said that there's -- you're not aware of any organism-specific issue related to Bair Hugger. I'm not asking about the Bair Hugger.

I'm asking about the interventions that Wansbeck General Hospital took in an effort -- in a series of efforts to reduce their extremely high infection rates, some -- some of which were targeted at specific types of organisms.

But you're saying that there's no organism-specific issue there that you need to look at; right?

A I was saying that the data for overall infection in the face -- in fact, as -- as you

mentioned, some interventions that might have lower infections, it was still -- the -- the magnitude of the increase was still substantial. I don't quite understand this.

Q The magnitude of the increase was still substantial just disregarding whether particular types of infections had increased or decreased.

Is that what you're saying?

MS. CONLIN: Objection as to form.

Go ahead.

THE WITNESS: And, again, I've not seen analyses, unless I'm missing them, of the actual rates of different types of infections in the -- in the two periods. And if such exist, they would be compromised by numbers.

BY MR. GORDON:

Q Let's talk about that number, the 3.8.

How is that amount computed?

A It's computed as the -- it's computed as the odds ratio, as I recall -- let me just pull it up and make sure I'm right --

Q Yeah. Yeah.

A -- of the -- of the rates and the two time periods of deep joint infection.

Q And the rates are based on the number of

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infections in the reported surveillance period divided by total number of procedures performed during the period; right?
A Correct.
Q And in the McGovern paper, what was the rate for the HotDog only period?
(Witness reviewing document.)
THE WITNESS: I --
BY MR. GORDON:
Q If it's taking too long, it's on page 5042.
A 0.8.
Q And that's based on how many --
How -- how is that 0.8 derived?
A That is 3 over 268.
Q Okay. What was the rate for the HotDog only period?
A I'm sorry. That's -- that was the HotDog period.
Q I'm sorry. I misspoke.
What was the rate during the Bair Hugger period?
A 3.0.
Q 3.0?
A That's correct.
Q Okay. And what was the -- what were the --

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What was the equation that --
A Well, it's 32 over 1,034.
Q Okay. And so tell me how -- how the calculation gets to 3.1.
A Oh, it's calculated -- it's the odds ratio divided by 2. --
Q I -- I misspoke. 3.8; right? The average that you're using is 3.8; right?
A Correct.
Q Divide that 3 percent -- or 3.0 by 0.8; right?
A No. It's the odds ratio from the table.
Q Well, how -- how was that -- that 3.8 odds ratio derived?
A There's an underlying 2x2 table with warming device, yes/no; infection, yes/no. And then it's calculated as the odds ratio from the table.
Q But I'm just trying to understand, What -- what are the numbers that are plugged in?
A The numbers are the -- sure. The numbers are the 321034 and the 3368.
Q Well, is -- is there any relationship between 3.0 and 0.8 in terms of coming up with the odds ratio?
A The -- are you asking for how an object was calculated?

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Q Yeah.
A So it is -- it comes out of the table that describes. And it's simply the cross-product of the diagonals.
Q Does it have anything to do with the ratio of 3.0 to 0.8?
A Well, the same -- the same numbers are -- the same numbers are involved, yes.
Q And that if that -- if the -- for example, if the 0.8 number were higher, the odds ratio would go down, wouldn't it?
A It would be a different data set, but yes.
Q Okay. Well, do you recall when you read Dr. Reed's testimony that he said that there was -- that the numbers weren't quite correct, there was actually one more infection in each group?
A I'm aware of that discussion, yes.
Q Well, were you aware of it before you wrote your report?
A I don't think I was.
Q Okay. So you're aware of it now?
A I'm aware of it now.
Q You became aware of it because you read Dr. Holford's report?
A I -- probably Holford's report brought my

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attention to it.
Q So you hadn't read -- either hadn't read it or just --
A I -- you know, again, I -- I remember some discussion about data sets. And I don't know what is the, quote, "correct" -- "correct data set." But I'm aware that Reed commented about the data.
Q Okay. If you add one infection to each group, what happens to the odds ratio?
A That's -- you know, again, I mean, that's not a question that could be answered generically. I mean, if we calculate it here, I suspect that since 3 is a very small number, adding 1 to make it 4 would lower the odds ratio.
Q Well, why don't you take a look at Dr. Holford's report here.
Is that Exhibit 4?
MS. CONLIN: Exhibit 3.
BY MR. GORDON:
Q 3. And if you'll look at page 3, Footnote 1.
(Witness turning to page.)
BY MR. GORDON:
Q For the moment, I don't want to ask you about Dr. Holford's calculation based on his analysis of the data set and the -- all the other things. He's

just -- Footnote 1 is just based on Dr. Reed's testimony that was one more infection in each group.

Do you have any reason to think that Professor Holford screwed up the calculations that he did there?

A Oh, he certainly did the calculations correctly.

Q Okay. And assuming those --

Well, first of all, do you have any reason to think that Dr. Reed testified inaccurately?

A I can't comment on that.

Q Okay. Well, if -- if -- if that testimony is accurate and Dr. Holford's calculations are accurate, the odds ratio would be 2.86; right?

A According to the calculation shown here, yes.

Q And the confidence interval would be 1.03 to 8.33; right?

A As described here, yes.

Q Is that -- would you say that's a strong association or moderately strong association, one that would allow you to feel comfortable in saying there couldn't be any confounders that can account for this odds ratio?

A My only comment is 2.86 is lower than 3. -- 3.8.

Q And a confidence interval that starts at 1.03 is just barely meaningful; right?

A I don't think meaningful is determined by the confidence level. Perhaps as significant as 3.05 is, but meaningful, no.

Q Okay. But your report was predicated on the assumption that the odds ratio of 3.8 was accurately reported in the McGovern paper; right?

A It was based on a report in a peer reviewed paper, correct.

Q Okay. And based on the testimony of Dr. Reed at least -- and there are -- and -- and there are other documents that Dr. Holford refers to that corroborate at least his -- his point about there being one more in -- in HotDog -- based on that and the calculations, the -- this -- the odds ratio is at best 2.86; right?

A Well, in this -- in this recalculation adding one more event to each group, it's 2.86, correct.

Q Does that give you any pause that adding one more infection to each group causes the odds ratio to go from 3.8 to 2.86?

A I don't know about giving any pause. But I've commented before that these events are not -- are not so common. So it's not surprising that the odds

ratio would drop with the addition of one event to the HotDog period when there's very few events there.

MR. GORDON: What number are we on? 5. Let me show you what's been marked as Exhibit 5. This was previously part of -- of the McGovern exhibits, which did not have unique exhibit numbers for a multiseries of pages.

(The aforementioned document was marked Exhibit 5 for identification by the reporter.)

BY MR. GORDON:

Q But you did indicate that you had available to you the McGovern testimony and the McGovern exhibits, and there was some discussion -- there was some testimony about this.

Do you recall seeing this, Exhibit 5, prior to today?

A I think I've seen this.

Is this the sixty-day moving average data?

Q No. That would be Professor Holford's report. This is --

MS. CONLIN: This is Exhibit 21 from the McGovern deposition.

THE WITNESS: Okay.

///

BY MR. GORDON:

Q Well, let me see if this helps refresh your recollection. Why don't you -- you know what, Ms. Conlin pointed out to me before we just broke that I had marked an exhibit from Mr. Albrecht's deposition where there was actually writing on it from Mr. Albrecht. So I didn't copy that.

MR. GORDON: So this one, I want you to have a copy available to you -- to you. So I'm going to give you Exhibit 6. I will hand you Exhibit 6, which is the same McGovern paper we've been talking about, but it just has no writing on it the way the one in ours did.

(The aforementioned document was marked Exhibit 6 for identification by the reporter.)

BY MR. GORDON:

Q And I would like you on Exhibit 6 to turn to Figure 7, which appears on page 1843.

(Witness turning to page.)

BY MR. GORDON:

Q Does this refresh -- refresh your recollection as to whether you saw Exhibit 5, this version of Figure 7 where the infection rate is reflected as a -- as a moving average as opposed to

a -- a uniform average across the entire Bair Hugger period?

A I'm not sure that that -- at this -- at this point, I've seen some of the Holford moving average figure as -- well, I -- I do think I've seen this figure before, and I think I remembered the comment about the, quote, "jittering" in the -- indicate the points.

Q I -- the jittering came from Albrecht's testimony.

A Okay. Well, as I said --

Q And -- and the -- and the reason I want to be -- I want to clarify is that Mr. Albrecht did testify about -- about Figure 7 as it was published, but at the time of his deposition, we didn't have what's been marked as Exhibit 5. We only got that afterwards. We got that from McGovern. So the only -- the only person who would have testified about it is -- is Mr. McGovern -- Dr. McGovern.

So I don't want to -- there was -- you're right, there was testimony from Mr. Albrecht about jittering. It wasn't in connection with Figure 7. It wasn't in connection with Exhibit 5.

A Okay.

Q So whether you've seen Exhibit 5 before or

not, looking at --

MS. CONLIN: He said he has seen it before.

BY MR. GORDON:

Q And I'm saying whether you have or you haven't. I --

MS. CONLIN: Well, object to the form of the question then.

MR. GORDON: Okay.

Q My -- my point is my question is not going to depend on whether you've seen it previous to today. So I'm not -- that's not where -- where I'm going with this.

Would -- in your view as an expert in epidemiology, does Figure 7 as published convey a -- a more useful and more accurate picture for the reader than Figure 7 as reflected in Exhibit 5?

A I guess there are a couple of comments. I probably need more information about what Exhibit 5 comprises. It says a moving average. I'm not sure of the window.

I assume this is Wansbeck. The numbers are -- 1290 is not what you would get by adding up what is in Table 2 of the McGovern paper, so I'm not quite sure what Exhibit 5 portrays.

Q Well, in fact, if you look at the start date on Exhibit 5, it starts September 2008; right?

A Yes, it does.

Q Whereas what they published actually starts in July of 2008; right?

A Correct.

MR. GORDON: Now, let me show you Exhibit 7. And this too is included in the large McGovern exhibits, whether you -- you saw it or not.

(The aforementioned document was marked Exhibit 7 for identification by the reporter.)

BY MR. GORDON:

Q I guess the question, that you recall -- you recall seeing this before?

A I'm sorry. Would you --

Q Have you seen this before, Exhibit 7?

A I think I've seen this.

Q Do you recall any testimony about email where Mr. Albrecht was telling Reed and McGovern, Scott Augustine, and Christopher Nachtsheim (reading):

"Barely made it with the new sampling numbers"?

A I -- yeah, perhaps I'm just simply not sure.

Q Okay. Do you recall reading a portion of the email where Mr. Albrecht says (reading):

"Okay. We made it here to a significant difference, so I'll update the manuscript to reflect the new infection numbers."

Do you recall reading that before?

A I -- I may have. Frankly, I'm just not sure I did. Whether -- you know, again, I -- looking -- looking through so much materials, but I'm just not sure.

Q When you do epidemiological studies, do you wait until you gather enough data to show -- you make it to a statistical significance?

MS. CONLIN: Objection as to form.

THE WITNESS: The only comment I'd make is typically there would be a protocol that would dictate that, like -- like the data collection.

BY MR. GORDON:

Q Did you see the protocol for the McGovern paper?

A The underlying protocol for study.

Q Do you know if one even exists?

A I can't comment on that.

Q So in terms of the start date, do you have

any idea when they started looking at the data, what start date -- whether there was a start date that was pre-chosen?

A My understanding of the start date is that it corresponded approximately, I think, to the implementation of the surveillance system.

Q Well, now I want you to go back -- again, we're comparing Exhibit 5 to the published version of Figure 7 in Exhibit 6 -- or -- excuse me -- Exhibit 7.

There are two different start dates; right? September 2008 and July 2008; right?

A If you're --

MS. CONLIN: Objection as to form.

THE WITNESS: Your question is, Is the start -- Is the start date in Exhibit 5 September 2008? And that in Exhibit 6 is July 2008.

BY MR. GORDON:

Q Oh, it -- I'm sorry. I misspoke. It is Exhibit 6.

Okay. So now let's go to Professor Holford's moving chart that we've been talking about, which I believe it appears on page -- you'll find it on page 13 of his report.

(Witness turning to page.)

///

BY MR. GORDON:

Q So first of all, what's your understanding of what this chart on page 13 of Professor Holford's report depicts?

A Well, I need a minute to go back and reread this --

Q Okay.

A -- before I comment.

(Witness reviewing document.)

THE WITNESS: Okay.

BY MR. GORDON:

Q What's your understanding of what this chart depicts?

A My understanding is that this chart depicts values for a chi-square calculated on a 2x2 table that involves different starting points for the period over which events are counted for the Bair Hugger device.

Q Okay. And the -- that red line, what does that -- what does that reflect?

A That's the value that the chi-square specifically needs to obtain the statistically significant -- less than .05.

Q So based on this chart, a start date of -- would a start date of 7/1/2008 be above or below the cutoff for statistical significance?

A Well, it looks like it would be slightly above.

Q Okay. And if you -- if the start date was August 30, 2008, would it be above or below?

A That particular value would be -- well, I think it's reflecting the somewhat, you know, variable numbers and the fact that these infections are not very common. But it would be below.

Q Okay.

MR. GORDON: We have 9 -- 8. I'll show you what's been marked as Exhibit 8, a document entitled "Infection Graph." It's part of the McGovern exhibits.

(The aforementioned document was marked Exhibit 8 for identification by the reporter.)

BY MR. GORDON:

Q Do you recall seeing this before?

A I -- not specifically, no.

Q What I want to draw your attention to in particular is the statement in Mr. Albrecht's email to Dr. Reed. He says in the second sentence (reading):

"For example, in the first data file you sent me, there were a total of N equals 4,263 surgeries

from 10/1/07 to 10/30/2010. In the second date" -- "data set, the dates are unlisted and there are N equals 4,444" -- "63 surgeries. These totals do not match."

Do you see that?

A I do.

Q Okay. Now you testified earlier that you had seen a data set --

MR. GORDON: I'm going to mark as Exhibit 9 what has been previously marked as Albrecht Exhibit 10.

(The aforementioned document was marked Exhibit 9 for identification by the reporter.)

BY MR. GORDON:

Q My question to you is, Does this appear to be the data set that you're referring to that you saw after you wrote the report relative -- relative to --

A I think -- the comment on here making it thus far similar to a large spreadsheet like this.

Q Okay. Well, what's the start date on Exhibit 9?

A It's October 1, 2007.

Q Okay. And that's the start date of what

Mr. Albrecht says to Dr. Reed was in the first data file that he sent from Reed to Albrecht; right?
A Correct.
Q If you use that data set based on Dr. Holford's -- Holford's graph, if you were to start the data analysis in October of 2007, would it have been statistically significant?
A Which date?
Q October 1 of 2007.
A Until -- until somewhere in 2008, none of the high score values are above the red line.
Q Yeah.
To cut to the chase, the only way, using the data starting in October 1, 2007 -- the only way you get the statistical significance is if you lop off the first nine months and don't -- don't start until July 1, 2008; right?
MS. CONLIN: Object as to form, it misstates the record.
THE WITNESS: I mean, my comment is that the -- you know, the line where the high score value is starting in 2007 is not clearly above that section until somewhere around 2008, yes.
BY MR. GORDON:
Q Yeah. I -- I want to -- ultimately what I

want to ask you about is whether in your view this is the appropriate -- the proper way to do a statistical analysis in observational studies.
You have data going all the way back to October 1, 2007. At some point, you're contemplating starting your data set in July 2008. You're -- you're -- at some point, you're contemplating starting the data analysis somewhere in 2008. Ultimately, you go with July 2008 as the starting point.
And July 2008 just happens to be the first time in this data set that you cross over or, in the words of Mr. Albrecht, "barely make it to statistical significance."
And if you did wait until August, it actually dips back under statistical significance, and you'd have to wait until October 2008 to start again. And even then it dips back down in your statistical significance. It doesn't stay permanently above it until -- until the -- early 2009.
MS. CONLIN: Objection as to form.
THE WITNESS: So what I'm --
MS. CONLIN: No. Hold on.
Objection as to form, and I object to the premise of that question to the extent that you're suggesting that the data in 2007 is complete.

BY MR. GORDON:
Q Dr. Samet, is this the way you do epidemiology? You get your data and see what -- you know, see what you need to -- to use --
MS. CONLIN: The same --
BY MR. GORDON:
Q -- to make it -- to make it -- to -- to barely make it to statistical significance?
MS. CONLIN: Same objection. Object to premise of the question.
THE WITNESS: I -- I mean, to step back, I thought the start date corresponded with the implementation of the surveillance system that went into play. That was in 2008, if I recall correctly.
So in terms of when it started, when the surveillance -- when the surveillance started I thought was the starting point may be optimized to -- for the -- for that data.
I mean, I think if your general question is when looking at data how it's approached in an analysis, it's usually per protocol.
BY MR. GORDON:
Q And you have no evidence that there ever was a protocol for this, though; right?

A I don't have evidence one way or the other.
Q Have you seen any testimony that this was -- the observational component of the study was done after the fact, after they had done the bubble study, and they decided, well, let's take a look and see if we can --
A I don't know about the time the exhibit was published.
Q Well, going back to my original premise -- well, I want to clarify something.
Your understanding is that some formal surveillance program started in July of 2008?
A Somewhere in there. And, again, I might be off. But I thought they identified two surveillance nurses who began an active surveillance program. Governor Reed speaks to this.
Q And when do you think that was?
A I think it was 2008.
Q I'll show you what I've marked as Exhibit 10.
(The aforementioned document was marked Exhibit 10 for identification by the reporter.)
BY MR. GORDON:
Q Have you seen this document before?
A I have.

Q When did you first see this? Before or after you wrote --
A After.
Q What was it that you --
What -- what caused you to review this afterwards?
A I think this was provided by Jan Conlin.
Q Okay.
MR. GORDON: And I'm going to give you Exhibit 11. And I will represent to you that Exhibit 11 is just a printout of the chart that appears on the second page of Exhibit 10. It's just for me a little bit easier to read. I don't know. Maybe your eyes may be a lot better than mine, but...
(The aforementioned document was marked Exhibit 11 for identification by the reporter.)
BY MR. GORDON:
Q Is this the -- the source of your recollection as to when the surveillance period began?
A I actually thought I saw it in either Reed or McGovern's reports or depositions.
Q Okay. And your recollection is they would have testified that that began in July of 2008?

A Well, as I said, I wasn't sure of the date, but that was my recollection.
Q Well, based on what you're seeing here and whatever you're characterizing as the surveillance, the formal surveillance, that wouldn't have taken place until at least December of 2008; right?
MS. CONLIN: Objection to form --
THE WITNESS: I'm sorry.
MS. CONLIN: -- it misstates the record.
(Witness reviewing document.)
MS. CONLIN: Is there a question pending?
MR. GORDON: Well, I don't know. He was reading, but...
THE WITNESS: Trying to read.
BY MR. GORDON:
Q Well, let -- let me see if we can speed this up.
On the first page of Exhibit 10, the right-hand column, first full paragraph says (reading):
"In 2008, hospitals were required by the HPA," which is the Health Protection Agency, "to identify and include patients who were readmitted with an SSI, and

further emphasis was put on organizations to use the data to evaluate local practice and institute changes that are required."
Do you see that?
A Yes.
Q Okay. If you drop down to the -- to the last -- the last full paragraph on the page, it says (reading):
"During the last two quarters of 2008 and 2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in THR, TKR" -- or total hip and total knee -- "and repair neck of femur between 3.5 percent and 5 percent and was regularly receiving letters from the HPA informing the trust of its high outlier status for SSI.
"As it was performing approximately 2,200 hip and knee replacements, every year implementing robust surveillance in

the SSI became a priority for the orthopedic team and the trust."
I'll continue on to the next page, where it says (reading):
"Following the correspondence from the HPA requesting action and the attendance of a group of clinical stuff at an SSI conference in Birmingham held by Patient Safety First, the SSI group was formed.
"A multidisciplinary team formed the trust's SSI group, and the first meeting took place in December 2008. This group was chaired by a proactive orthopedic surgeon and included a consultant, microbiologist, senior managers, infection control leads, matrons, and" -- "matrons, and clinical leads from operating theaters.
"Prior to the designated team of surveillance staff, surveillance of the mandatory reporting to the Health Protection Agency, as it was

then known, was being completed by personnel while they were still doing their regular work. There was no ownership of the process and the assurance in the validity of the results.

"The first action point of this meeting was to place a successful bid to appointment two full-time SSI nurses, i.e., twelve months secondment therefor."

Based on what I've just read, if this is correct, the surveillance -- the formal surveillance that you're talking about didn't take place any earlier than December of 2008; correct?

MS. CONLIN: Objection as to form, and it's a misstatement of both this document and his prior testimony.

THE WITNESS: I -- based on what's in this document, it appears they appointed the two full-time nurses somewhere after the first meeting.

BY MR. GORDON:

Q So whether the surveillance -- well, if -- and -- you're -- you're --

Are you thinking that Dr. Reed or Dr. McGovern testified differently?

A I would have to go back and look.

MS. CONLIN: Well, and as you know, Mr. Gordon, I think this is highly misleading because you know Dr. Reed, who you said testified to a July date, is not at Northumbria. Janet Matt was the one.

MR. GORDON: That wouldn't be a speaking objection, would it, Ms. Conlin?

MS. CONLIN: Well, I -- I think it's really misleading to do that to a witness.

BY MR. GORDON:

Q So whether the -- strike that.

You -- you read -- I think you said you read Dr. Holford's report --

A Yes.

Q -- in some detail --

A Yes.

Q -- as opposed to Professor Borak's --

A I read both reports.

Q Right. But I thought you said you spent a little more time with -- I don't want -- whatever words you used. But you --

A I think I referred to the Wenzel report.

Q Fair enough.

Do you have any criticisms of Professor Holford's report? Any points where you flatly disagree with him?

A I -- I think that's a question that's not answered with a simple yes or no.

I understand what Holford has done. And I think he's clear more or less in his descriptions of what he has done.

And -- and there's also a -- a peer reviewed publication that as a result has gone through the test of peer review.

Q With Rothman you know that the numbers were used in the peer reviewed publication were not accurate; right?

MS. CONLIN: Objection; it misstates --

THE WITNESS: Well --

MS. CONLIN: -- the record.

THE WITNESS: -- you know, again, I -- the statement from Dr. Reed and the questions about the data set, I, frankly, don't know why there's problems with the data set or why these issues are being raised.

But there's at least one investigator who said there might be a problem. And I don't know

the basis for that statement.

BY MR. GORDON:

Q It wasn't just one of the investigators, was it?

THE WITNESS: May I have some water?

MS. CONLIN: Okay.

THE WITNESS: May I have a break?

MS. CONLIN: Yeah, we can do -- yeah.

Well, are you going to a new area? Can we take a short break? We've been going now for a couple of hours.

MR. GORDON: Let me finish this up here. Exhibit 12; right? That's 12.

(The aforementioned document was marked Exhibit 12 for identification by the reporter.)

BY MR. GORDON:

Q And you might have seen this in the large McGovern production. But my question is whether you have -- you recall seeing it before. And in particular I want to address -- address your attention to the statement where Mr. Albrecht says to Mike Reed (reading):

"I've done a quick analysis of the new data, and the trend does

persist. But the data files are not totally consistent (in regards to the data the BR JBJS article was based upon.

"I checked the files side-by-side over the common time periods, and they do not match up for dates, etc. In fact, in the data file you sent me, the infection rate during the forced-air warming period was slightly lower than the previous one.

"Additionally, there is not a date associated with most infections (just a yes response for about 50 percent of the infected cases). So clipping at sixty days cannot be done.

"So I'm giving you a graphic for the Wansbeck data, but do not distribute it for a 'slightly" conflicts with the study data due to different reporting practices in your data.

"The relevant info supporting the figures of the infection odds ratio FAW to CFW equals 2.98, 95 percent confidence level, 1.36 to 6.53. P value for this odds ratio is now 0.0062 based upon a wall test."

And he says (reading):

"I'll look at the hip and knee separately next."

Have you seen this before?

A I -- I think so, yes.

Q And do you recall Mr. Albrecht's testimony about discrepancies in the data set, those used for the publication?

A At this point specifically -- at this point, again, it would be hard for me to sort out what I've seen and where.

Q Okay. Let's go back to Dr. --

MR. GORDON: All right. We'll take a break.

THE VIDEOGRAPHER: The time is 3:04 p.m. We are off the record.

(A brief recess was taken.)

THE VIDEOGRAPHER: We are back on the

record. The time is 3:17 p.m.

BY MR. GORDON:

Q Dr. Samet, were you aware before your report that the Laminar [phonetic] flow system in one of operating rooms at Wansbeck that had been malfunctioning had been repaired during the Bair Hugger only period?

A No, I'm not. I did not.

Q So, obviously, you couldn't have taken that into consideration in determining --

A I had no knowledge of that.

Q Okay. Were you aware that the -- prior to writing your report that they changed the wound dressing used after knee and hip surgeries at Wansbeck during the Bair Hugger only period?

A I think I became aware of that change afterwards, but perhaps from reading Exhibit 10 or something else.

Q By "afterwards," you're talking about --

A After March 30.

Q Okay. And have you been -- become aware at any time that Dr. Reed has publicly stated that he switched the wound dressings after he ran a study that demonstrated that there was a significant reduction in joint infections with the use of the newer wound

dressings?

MS. CONLIN: Objection; it misstates the record.

THE WITNESS: I am not aware of Dr. Reed's pronouncements on that.

BY MR. GORDON:

Q Okay. And I take it you have done no independent research to -- at this point to see if the wound dressing change could have been a confounding factor?

A I -- nothing specific, no.

Q Okay. Do you know --

Did you know prior to writing your report that they had changed the policy with respect to surgical personnel wearing their own personal shoes and required them to start using dedicated clogs that were left in the OR and washed in the OR?

A I became aware of some of this -- these procedure changes, again, after the March 30 report.

Q Would you agree that in terms of infection control, that there are a number of practices that have been developed and -- and implemented over time that individually might not have statistically significant robust evidence to demonstrate that they and they alone have an impact on a positive impact on

infection rates, but that when you do a care -- a care bundle, that it's the care bundle, the whole panoply of things, that that can have a significant impact on overall infection rates?

A That may be true, but I've done no particular relevant assessment of the literature on that topic.

Q Would you consider yourself an expert in the area of, you know, hospital infection control practices?

A I think I already replied to a similar question.

Q It was similar.

A I said no.

Q Okay. So whether care bundles that have a whole series of practice changes, whether they impact overall infection rates in hospitals or not, that's beyond your scope of -- of what you're going to be offering an opinion on?

A Not something that I specifically -- I specifically looked at.

Q Okay. And I apologize. I -- I'm going to sustain her objection of asked and answered. I was starting to forget.

Did you know before you wrote your report that the MRSA screening had been implemented?

A Oh, I can't recall.

Q Okay. Have you -- did you review any literature that looked at the impact of prewarming on maintenance of normothermia?

A Along the way, I've looked at that, and I read the Kurtz paper, among others, trial. Looked -- looked at that issue of warming and prewarming only superficially.

Q And -- and you mentioned Kurtz. I wonder if you meant Mella [phonetic] on prewarming.

A No. I was actually thinking about the Kurtz paper. I guess it's not prewarming per se.

Q And my question was -- and I apologize. What -- what I'm asking you about is -- and your answer presumably would be the same. I just want to be clear.

Have you done any research into more -- more recent literature as to whether the combination of prewarming and active warming during surgery is more or less or equally efficacious in terms of maintenance of normothermia than just warming during surgery?

A No, I have not.

Q So did you know before you wrote your report that when they switched to the Bair Hugger strike -- strike that.

Did you know before you wrote your report that when they switched from Bair Hugger to HotDog with the Hot- -- with the implementation of the HotDog at Wansbeck, they also implemented the addition of prewarming?

A No. I don't know those details, no.

Q Now, you said you saw Exhibit 10 and the chart in Exhibit 11 after you wrote the report; is that right?

A Yes.

Q Now, am I -- I'm correct that you have not looked at any published data from Great Britain or the National Health Service on infection rates at all; right?

A I don't think so. I may have -- I -- there may have been -- I'm trying to recollect. I may have seen a National Health Service annual report along the way, but I'd have to refresh my memory on that.

Q Okay. Well, if you look at Exhibit 11, the chart, would you agree with me that the -- the line that shows the SSI percentage for each quarter reflected there is -- there's a -- there's a fair amount of up and down movement?

A There's some variation of the line, yes.

Q And if this is accurate, this would indicate

that in the second quarter of 2012 their infection rate spiked back up over 3 per- -- over 3 percent; right?

A Well, the -- the line went up, and there's presumably some instability as -- in these numbers over -- over time. I'm just trying to --

Sorry. Let me make sure I understand what this line is.

(Witness reviewing document.)

BY MR. GORDON:

Q Yeah. And -- and I don't want to mislead you. This -- this is not just giving knee, although I believe that most of it --

A Yeah, surgical.

Q But it includes neck pain -- repair of neck pain.

A Well, it says surgical site infection. It doesn't say deep joint infection.

Q Yeah. I guess you have to look at the text and the NHS reporting requirements and I think Dr. Reed's testimony.

Rather than me looking at Exhibit 11 or actually discussing what that does or doesn't say, based on everything you've seen, wouldn't you agree that the data for joint infection rates throughout the

Bair Hugger period was -- had -- had instability, to use your word?

MS. CONLIN: Objection as to form.

THE WITNESS: Well, I -- it's variable. I mean, I don't know whether the word is "instability." But the -- the rates that -- the line varies in terms of the number, which is not -- not surprising in terms of a relatively uncommon event.

BY MR. GORDON:

Q Given that it's a relatively uncommon event and given that the -- there's the variability that you've described, would you -- doesn't that make it a lot harder to conclude that if you just look at one period and treat it as a monolith in terms of the average infection rate and look at some other period and say whatever difference you see is attributable to one change when there's been a lot of variability and a whole bunch of other changes that could have had impact, you know, on particular types of infections or as a care bundle on overall practices? Wouldn't you agree that that's not proper -- that's not a proper application of epidemiology?

MS. CONLIN: Objection as to form, it misstates the record.

THE WITNESS: I mean, I'm -- yeah, can you help me with what the question is.

BY MR. GORDON:

Q Well, when you drafted your opinion, you reviewed the McGovern paper as it was published. You didn't have the benefit of some of data we've gone through. You hadn't read some of the -- the testimony the specifically relates to that testimony.

Now you -- at this point, you've gone through some things that would demonstrate that there was significant variability, that if you look at the types of infection -- I guess you haven't. I've given you a document to look at that and see if you can do that -- types of infection vary over time.

The -- and given all these things, do you still believe that -- that proper application of -- of epidemiologic methodology leads inexorably to the conclusion that it's the Bair Hugger and the Bair Hugger alone that just nearly quadruples the infection rate?

A Well, I think I'm going to answer your question. The way to deal with the variability in small numbers is to take the average across the period of observation. And that's going to be the best estimate of way things usually are.

So the fact that -- the somewhat variable estimates of counts, essentially, were averaged. There's what? Thirty-two, thirty-three events across the McGovern Bair Hugger period.

It's not surprising that there is some -- some variability in this -- in the data. So the best way to try to understand what's happening -- they're reasonable. But to me that is a reasonable average.

Q So let's go back to Professor Holford's report. And take a look at his page 12, the chart that he identifies as Figure 2.

(Witness turning to page.)

BY MR. GORDON:

Q I think earlier you had made some reference about a two-moth moving average or a sixty-day moving average.

Is this the -- the chart you were thinking of?

A That's the figure -- the figure with the sixty-day average, yeah.

Q Okay. Do you have any quarrel with how Professor Holford has plotted this?

MS. CONLIN: Objection as to form.

THE WITNESS: I'm not sure about quarrel. I mean, I -- it's clear it states clearly what was

done.

BY MR. GORDON:

Q Okay. Well, based on everything you know, do you think what he did was erroneous for any reason?

A I think what he's done is display the average in a line that shows a sixty-day moving window average.

Q And do you -- when you -- when you take a look at that line, it looks like there are kind of two peaks, one far more pronounced at the very end of the Bair Hugger period; right?

A Well, this -- yeah, there's some movement in the -- in the -- in the average. It dips, and it goes back up.

Q Well, from April or mid 2009 when there seems to be a fairly low point in the moving average to the high point in early 2010, that's a -- that's an enormous swing, isn't it?

A I don't know about enormous. I mean, you know, when we look at these specs, we're going from less than 2 percent up to 4 percent, 4 1/2 percent.

And, you know, some of this is the intrinsic noisiness of the data, which is why I wanted an average.

And I -- you know, again, my comment earlier

about the surveillance time in Wansbeck, I thought it started in October '08. I just -- which is why I had wondered with that -- somewhere in 2008 with the lower rates earlier in the year.

But in any case, I mean, yes, there's some variation in this moving average.

Q And from a statistical standpoint, you're -- you think that the proper way to analyze these data is to just say "Well, we'll just" -- "we're just going to compare the overall average of a twenty-month period that goes up and down and up to a seven-month period"?

A No. Let me say --

MS. CONLIN: Well, objection -- objection as to form in terms of the time.

THE WITNESS: Sorry. Forgive me. Just restate the question for me.

MR. GORDON: Well, I don't think it was accurate. So, Jan, if you want to enlighten me as to where I -- I misspoke I would be happy to --

MS. CONLIN: Well, I --

MR. GORDON: -- be educated.

MS. CONLIN: -- I can't tell from -- I don't want to have a speaking objection, but I think --

MR. GORDON: I'm inviting you.

MS. CONLIN: All right. The -- this chart starts on September 1st, 2007, which we think the record is pretty clear. And it's an inaccurate -- inaccurate data set for that. So that -- that was the issue, but I didn't want to --

MR. GORDON: Okay. No. I'm glad you -- and that's fine. Let's -- I will clarify -- clarify my question then. I wasn't -- that wasn't what I was intending to ask.

Q I'm talking about the twenty-month period that is depicted in Professor Holford's Figure 2 as the Bair Hugger study period. There's a red line across that corresponds to the study time period reflected in the McGovern paper. And that's a seven-month period that is identified here as the HotDog study. Those are -- are the two periods I was referring to.

And you've got twenty months of -- of data in the Bair Hugger study that go to a low, as you say, of, it looks like, less than 1 percent to a high of 4 or 5 percent during that twenty months. And then you've got -- and that's being compared to the average of seven months of data from McGovern -- or from the HotDog period.

Do you think from an epidemiological standpoint that averaging data with that kind of variability over twenty months and comparing it to a seven-month period is sound epidemiological methodology?

A Well, yeah, let me comment from a different perspective. I've done a lot of time series analyses.

This data set is simply too small to do any sort of formal analysis. It's small. It's -- I'll use the word "noisy." And probably the best way to get a stable signal is to average the data that is at hand.

Q When you have a small and noisy series, doesn't that impact the -- the weight that you can give to any conclusions from it?

A Well, again, as I said, the best way to try to understand what the signal is, is to average all the data you have and -- and use it all.

Q You're saying the best way under adverse -- the -- the less than ideal circumstances of having a small and noisy data set?

A I'm simply referring to the data at hand in this -- in this picture.

Q In your professional work, either your teaching or if you do health organization bodies like

that, would you recommend a change in practice based upon a single observational study that has this limited data set and is this noisy?

MS. CONLIN: Objection as to form, it misstates his report.

THE WITNESS: Yeah. Again, my conclusions as I've -- the conclusion of my report is not based solely on the McGovern data set. There's extensive review of other materials.

BY MR. GORDON:

Q Yeah, and we're going to -- and I -- and I am confining my questions to McGovern.

So if -- if you take had the McGovern paper out of your consideration, are you saying that your -- your opinion would remain the same, that the Bair Hugger is a substantial cause of surgical site infections, substantial to -- or to periprosthetic infections?

MS. CONLIN: It calls for speculation.

THE WITNESS: I -- I -- the only comment I could make is that there's now a second study, the Augustine report, with another -- an est- -- another estimate of the risks of this too. That's I think what I can say at this point.

///

BY MR. GORDON:
Q Okay. But what I want to understand is when you came to the opinion that you offered to the court on March 30, as I read the report, it -- the McGovern study is a critical element in how you arrived at your conclusions. But if I'm -- in fact, that's how I read it. That doesn't really matter.
A Yeah. That's --
Q My question to you, because you keep talking about it -- it's is just part of the data. If you didn't have the Mc --
If you hadn't had the McGovern paper at all, would you have, based on all the other stuff that you're talking about, arrived at the same conclusion on March 30?
A The McGovern paper is, at the time I wrote my report, the sole paper in the peer reviewed literature offering an estimate of the risk of deep joint infection associated with the Bair Hugger device.
Q So if you hadn't had the McGovern paper, you would not have reached the conclusions that you reached --
MS. CONLIN: It calls for speculation.
BY MR. GORDON:
Q -- on March 30; right?

MS. CONLIN: It calls for speculation.
THE WITNESS: I -- I could only -- I could only say that there would not have been anybody to -- absent the McGovern paper, to quantify the magnitude of this.
BY MR. GORDON:
Q Okay. But you would have still opined that there was a risk, just you couldn't quantify it?
A I just can't answer that question.
Q Well, let's approach it from a different standpoint. You've mentioned now several times that the McGovern paper was not the only evidence or data upon which you based your conclusion.
Tell me what the other body of -- of data is that contributed to your opinion.
A Well, let me take out my report --
Q Sure.
A -- and -- and comment on that. I think the sections lay out the different lines of evidence that were considered and perhaps --
Critically the idea is laid out in Figure 3 on page 21.
Q Okay. So table -- that table lists four sentences; right?
A No. I said Figure 3 on page 21.

Q Oh, Figure 3. I'm looking at page 3.
I'm sorry. What page?
A 21.
Q Okay. Okay. So you -- this is, you say, "Mechanisms by Which the Bair Hugger Increases Risk for Joint Infection"; is that right?
A That's the title.
Q And you have the first two arrows. One goes to disturbed unit or directional flow. The other goes to microbial contamination of a surgical field. Right?
A Correct.
Q Let's talk about the bottom, microbial contamination of a surgical field.
What do you mean by "microbial contamination"?
A Microorganisms.
Q Okay. And what data did you review that -- well, strike that.
Am -- am I correct in inferring from your depiction here in Figure 3 that you believe there are some evidence that the Bair Hugger device results in increased microbial contamination of a surgical field?
A Well, it is shown that -- the -- the literature cited shows that -- and -- and also the

computational fluid dynamics of modeling that there's increased flow of particles across the surgical field.
I believe at least one study -- maybe it's Moretti [phonetic] -- shows increased numbers of microorganisms associated with the Bair Hugger operating and then also the disruption of directional flow. So those contribute to increased risk of infection, which is what I've laid out here in Figure 3.
Q You -- you referenced computational fluid dynamics.
I take it you are referring to the computational fluid dynamics analysis that was done under contract to Dr. Al Garbashi [phonetic] at the request of plaintiffs in this case?
A That's correct.
Q I noticed --
MR. GORDON: Let me show you an exhibit I'm up to 13. Let me show you Exhibit 13.
(The aforementioned document was marked Exhibit 13 for identification by the reporter.)
BY MR. GORDON:
Q I noticed in your reference materials you cited to an unpublished document by Memarzadeh.

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And I want to know, first of all, Is Exhibit 13 that document to which you were referring?
MS. CONLIN: I'm sorry. What's the question?
BY MR. GORDON:
Q Exhibit 13. And take a look at your report there. On the reference list is a reference to some -- to some unpublished something from Memarzadeh. It's your Reference Number 51.
MS. CONLIN: He's just asking you if that -- the reference on there --
THE WITNESS: Well, I assume so. I'm just trying to read from the reference document.
BY MR. GORDON:
Q This is -- is Exhibit 13 what you listed as Number 51 on your materials considered?
A Appears to be the case, yes.
Q So this is something you had --
Exhibit 13 is something you had available before you wrote your report; right?
A Yes.
Q And if you turn to page 10 of Exhibit 13 --
(Witness turning to page.)
BY MR. GORDON:
Q -- it says (reading):

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"This investigation validates the results and conclusions drawn by Moretti and others that the forced-air warming technology does not in and of itself result in increased risk of surgical wound infection.
"However, this investigation further indicates that if the operating room ventilation system is designed properly, the contaminating particles from staph around the patient will not impinge on the surgical wound due to thermal plume dynamics."
So that -- you read that before you rendered your opinion?
A (No audible response.)
Q And -- and we can go through this.
But what this is, is a computational fluid dynamics study; right?
A Yes.
Q And staying on page 10, you see that under the conflict of interest statement, it says "undeclared"?

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A I see that, yes.
Q The CFD, the computational fluid dynamics, that -- that you referenced in your report -- or that you actually discussed in your report by Dr. Al Garbashi, if that were a published paper, you would -- you would agree he'd have to declare a conflict of interest if that was -- he did that -- he was paid by the plaintiff's counsel to do that for this litigation?
A He would have cleared his finances.
Q Well, don't you think that would be -- would constitute a conflict of interest?
A I -- I think that surmises that funding source influences the outcome of this computational fluid dynamic model.
Q Well, okay. Page -- page 10 on the Memarzadeh thing identifies the funding sources of the National Institutes of Health; right?
A (No audible response.)
Q You have to say yes or no.
A It does, yes.
Q Okay. But -- so -- and I guess I've seen this a lot where there's a conflict of interest statement and a funding source statement.
Is that -- are -- are you saying that there's

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view there -- if you declare your funding source, that's -- you don't have to declare any conflict of interest?
MS. CONLIN: It misstates his testimony.
THE WITNESS: No, I didn't say that.
BY MR. GORDON:
Q Okay. In fact, I -- the opposite is true.
Wouldn't you -- wouldn't you agree that it's customary to declare funding sources and to identify any conflicts of interest?
A Any potential conflicts of interest, right.
Q Do you think being an expert witness hired to testify on behalf of one side in civil litigation in and of itself is a conflict of interest -- a potential conflict of interest that would be -- that would ordinarily be declared?
A Well, I -- I think it's clear that the report was done for the plaintiffs.
Q You're talking about Dr. Al Garbashi?
A Yeah, Dr. Al Garbashi.
Q I -- for the record, my -- my point is, if it had been a -- a paper for use beyond this litigation, it would -- you would agree it should probably have a conflict of interest disclosure that it was originally prepared for litigation?

MS. CONLIN: It calls for speculation.
THE WITNESS: I can't say. Presumably I'm speculating.
BY MR. GORDON:
Q Okay.
A If he were to have published the paper, he would have revealed the funding source.
Q In the Memarzadeh paper that you listed as part of your references, the funding source is the National Institutes of Health.
What -- what is that organization?
A I'm familiar.
Q I know that sounds -- I don't mean it to sound sarcastic. I have to ask a basic line of questions.
A Yes.
Q Tell -- tell me what the National Institutes of Health are.
A It's a collective set of institutes that carry out research and fund the researches.
Q Who pays that, to support the National Institutes of Health?
A Taxpayers.
Q So it's a government-funded entity?
A Largely.

Q And you've done work funded by grants from the National Institutes of Health, haven't you?
A Yes.
Q Would you agree that the National -- the purpose of the National Institutes of Health is to objectively try to do and fund research for the improvement of the public health?
A Well, improvement of health generally, yes.
Q Okay. The National Institutes of Health is not involved in litigation.
The reason for -- for what it does has nothing to do with trying to help one side or another in litigation that prevail in court; right?
A Correct.
Q And do you know Farhad Memarzadeh?
A No.
Q Did you -- how did you come to be in possession of a copy of Exhibit 13?
A I really can't say sitting here right now.
Q Well, why is it that you chose to discuss the findings of a hired expert working for the plaintiffs in your report, but you said nothing in your report about findings of the computational fluid dynamics carried out by and fund -- by an employee of and funded by the National Institutes of Health?

A Well, frankly, I was impressed by the scope and elegance of the modeling done by --
How do you pronounce his name?
MS. CONLIN: Dr. Al Garbashi.
THE WITNESS: Dr. Al --
MS. CONLIN: Al Garbashi.
THE WITNESS: Al Garbashi. And, you know, I'm not in a position to specifically compare this analysis with the other, except that I will say that the other was -- Dr. Al Garbashi's was I -- I think far more intensive than the scope and computational approach.
And I actually will say that some of the findings here around no disruption of flow would be contradicted by some of the observations actually made in similar simulation studies.
BY MR. GORDON:
Q Tell me what --
Well, first of all, in what way is -- is Dr. Al Garbashi's CFD more elegant than the one from Dr. Memarzadeh of the National Institutes of Health?
A Well, I -- you know, I think a comparison will show --
And, again, this is outside of my -- CFD modeling is specifically not something that I would

place within my sphere of expertise.
But there's a much higher level of documentation and intensity to try and develop components and models that simulate operating room conditions.
Q What -- can you give me any examples of those elements that are present in Al Garbashi that are not present in the computational fluid dynamics model done by Dr. Memarzadeh?
A I think that even a superficial look at Al Garbashi's paper compared to this one will show far greater effort to develop the -- the equations that describe what is going on in the -- in the operating room there that are -- and that are simulated.
I mean, it's a very lengthy compilation and -- well, I have some ability to look at some of it. It's far more intense and deeply developed than this paper is.
Q And -- and you thought the difference in elegance in the things you described between Al Garbashi and Dr. Memarzadeh was -- was so stark, that it wasn't even worth a note in your footnote or some comment in the text of your discussion of Memarzadeh -- or Al Garbashi's CFD that, "Oh, by the way, there's an independent CFD done by the National

Institutes of Health that comes to a completely opposite conclusion"; right?

MS. CONLIN: Objection as to form, argumentative.

THE WITNESS: And I, frankly, would leave the computational fluid dynamic modelers to make their judgment. I gave you my view of why I looked at the Al Garbashi paper.

BY MR. GORDON:

Q Well, okay, we'll -- we'll -- fair enough.

When you were writing your report, did you view your role as one of trying to analyze the totality of -- of relevant evidence and apply your best judgment while at the same time noting the areas where there was potential reasons to question or temper the conclusions that you reached?

A I'm not sure I know what you mean.

Q Do you think your -- did you view your role --

In writing this report at the behest of plaintiff's counsel, were you -- were you an objective science -- scientist trying to address facts, good, bad, or indifferent, or were you trying -- or did you view your role as advocating for the plaintiff's position?

A I viewed my role as advocating.

Q But you viewed your role just specifically with respect to the CFD model as you, who is not an expert in CFD, deciding which CFD model was more elegant or more accurate or however you want to describe it?

A In depth.

Q In depth. The one by the hired expert for the plaintiffs versus the one done by the National Institutes of Health.

And your -- your conclusion about that was that the difference was so stark, that you didn't even have to, as an objective scientist, mention "Oh, by the way there's this completely diametrically opposed conclusion coming out of an independent CFD done by somebody who doesn't have a dog in the fight"?

MS. CONLIN: Objection as to form, argumentative.

THE WITNESS: It is included in the list of materials.

BY MR. GORDON:

Q It is included.

There's not -- but there's not a syllable about it in the text; right?

A It's not mentioned in the text.

Q Now, let's go back to -- well, I want to go back. You -- you said that -- words to the effect that -- I don't want to put words in your mouth -- but that the -- Al Garbashi's CFD was consistent with or confirmed by disruption studies. Again, whatever words you used.

But I want to talk about what -- what studies you're talking about that you believe demonstrates the correctness of the Al Garbashi CFD and why the National Institutes of Health's CFD is wrong.

MS. CONLIN: Well, objection as to form, argumentative.

THE WITNESS: Yeah.

MS. CONLIN: I mean, you've already talked to Dr. Al Garbashi about this specific issue in this report. I'm not sure why you're dragging Dr. Samet through it.

MR. GORDON: Dr. Samet discussed Dr. Al Garbashi's --

MS. CONLIN: Yeah.

MR. GORDON: -- report and described it as elegant. He said it formed part of the basis of his opinion.

MS. CONLIN: Is there a question pending?

MR. GORDON: Yeah.

MS. CONLIN: What is it?

MR. GORDON: Do you want to read it back.

(The record was read by the reporter as follows:

"Q. Now, let's go back to -- well, I want to go back. You -- you said that -- words to the effect that -- I don't want to put words in your mouth -- but that the -- Al Garbashi's CFD was consistent with or confirmed by disruption studies. Again, whatever words you used.

"But I want to talk about what -- what studies you're talking about that you believe demonstrates the correctness of the Al Garbashi CFD and why the National Institutes of Health's CFD is wrong.

"A. Yeah.")

MR. GORDON: I'm very impressed, by the way.

Q But the specific question was, What are the studies that you're talking about?

A So, again, the studies are listed in my

expert report related to -- I think Table 3 is the relevant -- the relevant table. Those are the various studies involving bubbles and parallel counts.

Q So Table 3 on page 24 lists four studies; right?

A That's correct.

Q Okay. And the first one is McGovern, which is -- there were two components to the study. We've been talking most of the day about the observational study.

A Yes.

Q You were talking here about the neutral buoyancy detergent bubbles. And then there are two studies by Legg and one by Belani; right?

A Correct.

MR. GORDON: Start with Exhibit 14.

(The aforementioned document was marked Exhibit 14 for identification by the reporter.)

BY MR. GORDON:

Q Is this the Belani study to which you were opining?

A That's correct.

Q Okay. And on the first page of this disclosure area, who does it indicate supported this

study?

A It is supported by Augustine Temperature Management.

Q What -- what was your --

When you wrote your report, what was your understanding of what Augustine Temperature Management was?

A I assumed it was Augustine's company.

Q The makers of HotDog? Did you understand that?

A Yes.

Q And you see for Mr. Albrecht --

And if I'm reading this legend properly, it discloses his affiliation as Bioinformatics and National Marrow Donor Program, Minneapolis, Minnesota?

A Apparently, yes.

Q Okay.

A It looks like.

Q Did -- did you know when you read this paper that when Mr. Albrecht did the work that resulted in this paper, the experiments, and the actual grafting publication, that he was an employee of Augustine?

A Sorry. That's not what -- the Bioinformatics and National Marrow Donor Program related to other statements.

I see he reveals under his conflicts. He said he received paid support. But assuming his position was elsewhere, if I'm reading the arrows correctly.

Q You are. And at the time that this was ultimately published, he was an employee of the bone marrow program.

But the -- but as you point out, under the conflicts of interest statement, not just the funding source that we talked about, it says that Albrecht received paid support salary from Augustine Temperature Management. So I want to --

You -- you knew when you read this that -- that an Augustine employee was involved in this; right?

A That was clear. And I knew a little bit about Augustine's history.

MR. GORDON: I'm going to show you Exhibit 15.

(The aforementioned document was marked Exhibit 15 for identification by the reporter.)

MS. CONLIN: I guess he's taking this back.

Do you want this all handed back?

MR. GORDON: Did we do that? We'll just -- we'll keep them just so the record is clear.

Q Exhibit 15 is actually the literature, Number 2 on your materials considered list; right?

A Yes.

Q But it's not one of the studies that you listed that you -- that appears on Figure 3 in your report or Table 3 -- excuse me -- Table 3; is that right?

A Correct.

MS. CONLIN: Yeah. You're on Legg 2012 and Legg 2013, I believe.

MR. GORDON: Right.

Q I just -- I want to clear up that the -- the -- the -- Exhibit 15, the -- the Albrecht 2011 paper, you -- it was material you had available to you.

Did it in any way impact your -- your opinions?

A You think it was part of the general background of papers addressing issues related to the Bair Hugger device.

Q Okay. Well, do you -- I -- I generally don't recall that we discussed filtration. This paper is

about filtration.
A Frankly, I don't either.
Q Did -- did you --
A But, I mean, I listed it in the materials. I certainly read this paper. I don't recall specifically citing that, but I would have to go through the report.
Q I didn't really mean to mark it. But since I did, I just wanted to find out.
Did -- do -- do -- does anything --
Any issue of filtration of, you know, the Bair Hugger unit, does that play any role in the opinions that you've come to?
A Well, you know, I guess potentially in that -- you know, this paper -- and I can't remember what other papers addressed the filtration issue -- questioned the efficiency of the filters.
MR. GORDON: Okay. I'll show you Exhibit 16. I've got it right this time.
(The aforementioned document was marked Exhibit 16 for identification by the reporter.)
BY MR. GORDON:
Q This is -- Exhibit 16, is that the Legg the 2015 paper that you included on your Table 3?

A Correct.
Q And when you read this, were you aware of any involvement in the underlying study that's reflected in Exhibit 16 of anybody connected to Augustine?
A Not that I recall, no.
Q And as you sit here today, was it your understanding that the -- Exhibit 16, the study reflected in there, was conducted entirely independent of anybody connected with Augustine?
A Well, looking at the report, I will -- I will say I don't know if there's a conflict of interest statement on file for these authors. But in the -- what I have in my hand, there's no mention.
Q But beyond -- my -- my question was beyond anything that might be in -- in the text or appear in --
A No.
Q -- Exhibit 16.
A It says (reading):
"No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article."
That's at the end of the text.

Q And it -- I just want to clear --
You have no additional information beyond that, and as you sit here today, as far as you know, this study was conducted without any involvement of -- with anybody connected to Augustine; right?
A Well, again, based on what is here, there's no mention of any connection to any commercial person, commercial entity.
Q And you're -- you're probably being precise, but -- and so I guess I need -- I want to be equally precise. I'm not asking what's mentioned here.
Do you have any independent source of information that would lead you to believe that there was any involvement with anyone connected with Augustine in Exhibit 16?
A I have no other knowledge of this paper other than what I have in my hand.
MR. GORDON: Okay. Now I want to show you Exhibit 17.
(The aforementioned document was marked Exhibit 17 for identification by the reporter.)
BY MR. GORDON:
Q This is a -- I hope I did it right -- the Legg 2013 paper that you referenced in your table; is

that right?
A Correct.
Q And in Exhibit 17, there's no indication of anyone or anything connected to Augustine had anything whatsoever to do with the study reflected in Exhibit 17; right?
A There's a similar disclaimer at the end of the -- at the end of the written text.
Q And my question is the same as it was for Exhibit 16.
Do you have any independent knowledge from any source beyond what is set out in the paper itself that would indicate that this was any connection between anybody connected to Augustine and the -- and the study that is reflected in Exhibit 17?
A The same answer. What I know about the paper is what I'm holding in my hand.
MR. GORDON: So now I'd like to show you Exhibit 18.
(The aforementioned document was marked Exhibit 18 for identification by the reporter.)
BY MR. GORDON:
Q This was previously marked as Albrecht Exhibit 32.

But Albrecht was one of the ones where you didn't have any exhibits provided to you; right?
A It's the one where I didn't list any of the exhibits.
Q Yeah. So let me start by asking you if you seen this before.
A I'm not sure.
Q Okay. I'll also direct your --
A I think it's on my list of materials considered.
Q Oh, okay.
A Yeah.
Q Did you say yes?
A No, it's not there.
Q Oh, okay. Well, the first page, as you can see, is an email from Mark Albrecht at Augustine Biomedical to Dr. Andrew Legg, Scott Augustine, Christopher Nachtsheim. And the text says (reading):
"Hi, guys. I think the manuscript is ready for first review. Please let me know what comments you may have. Thanks in advance."
And if you turn to the second page, there's a title page of something called

"Forced-air warming effective but risky. Patient warming systems and their effect on orthopedic Laminar ventilation." The authors listed are Andrew Legg, Andy Hamer, Mark Albrecht, and Christopher Nachtsheim.
Is this -- and my question now is, Is this the first that you've seen a draft of a paper with Legg, Hamer, and Albrecht as co-authors?
A I don't think I've seen this, yeah.
Q And I take it you have no knowledge that the activities that are reflected in Exhibit 17, the Legg, Hamer 2013 paper, the actual experiments that form the basis for it were conducted by Mark Albrecht and employees of Augustine Biomedical in conjunction with Andy -- and Dr. Andrew Legg?
MS. CONLIN: Hold on.
Are you representing that Exhibit 18 is the study reflected in Exhibit 17?
MR. GORDON: Yes, ma'am.
MS. CONLIN: I'm going to object. It assumes facts not in evidence.
BY MR. GORDON:
Q So have you -- I -- I -- the -- my question is -- I'm correct you haven't -- the -- my -- my telling you -- and counsel has evidence that shows

otherwise she -- she knows how to handle that.
But I'm telling you the evidence -- sworn testimony in -- in the record demonstrates that it was Mark Albrecht and Andrew Legg together who did the experiment that is described in Exhibit 17 and discussed in a draft created by Mark Albrecht in Exhibit 18.
You had no knowledge of that; correct?
A No. If -- if, in fact, these correspond, which I haven't had a chance to --
Q Yeah.
A -- make that judgment.
Q Would it matter? Not -- not the correspondence. But would it matter to you if Augustine personnel were involved in -- in both of the Legg studies that you cited?
A The -- my first answer is I don't -- I don't know whether it would matter if it raises the sort of potential conflict of interest concern. But that's all I can say.
Q Now, the four studies that you cite on Exhibit 24 -- or Table 4. Excuse me. Table 3, on Exhibit 1, page 24.
The McGovern paper, of course Mr. Albrecht of Augustine Biomedical was one of them involved in that;

right?
A Correct.
Q And you know that Albrecht was involved, and Belani is one of the co-authors; right?
A Correct.
Q And prior to today, you had no knowledge of any involvement of Mr. Albrecht or anyone from Augustine Biomedical in any of the Legg studies?
I represented to you that the August -- Augustine personnel were involved in the 2012 study based on his sworn testimony. And Mr. Albrecht and Dr. Legg together conducted the experiments reflected in Legg 2013.
A Yes.
Q If -- if my representation to you is -- is accurate, the record is -- is correct, does it concern you that all four studies that you're relying on as demonstrating there's a potential for surgical site contamination were conducted in some way with -- in connection to Dr. Augustine's company that was making a competing product?
MS. CONLIN: An objection as to form, it assumes facts not in evidence with respect to all these authors.
THE WITNESS: Sorry. Can you repeat it.

BY MR. GORDON:
Q I'll let her read it back.
A Okay.
Q You know what, no, I'll -- I'll rephrase it and make easier and less convoluted.
For purposes of my question, I would like you to assume that Augustine personnel were involved in the Legg 2012 study; that Mark Albrecht and Andrew -- and Andrew Legg together conducted the experiments that resulted in Legg 2013 paper; and Albrecht, an employee of Augustine, was involved both in McGovern and Belani.
If my representations are accurate, in other words, all four studies have connections to Augustine, does that give you any question or cause for concern about relying on these four studies as indicators of potential surgical site contamination with the Bair Hugger?
MS. CONLIN: The same -- the same objection.
THE WITNESS: I -- so at this point, I'm going to have to say that, you know, the postulated role for Albrecht in the other studies, I just have no any knowledge.
///

BY MR. GORDON:
Q I -- I understand.
A So I'm trying to preface my answer by --
Q I understand --
A -- saying that.
And -- and, secondly, at least if I understand, Albrecht -- what Albrecht has done is research. I thought it was largely as an analyst, which would not be surprising to find his name on multiple publications.
I guess it's another point if -- if the -- oh, gosh.
MS. CONLIN: This?
THE WITNESS: Exhibit 18 is, in fact, the -- a precursor to Exhibit 17. The decision-making around the authors would be of -- of interest, possibly of -- of concern.
I think the only other comment I'll make generically is that if you look at any papers related to products, whether it's on -- whether on pharmaceuticals or devices, the companies very often fund research, and sometimes they fund research directed at competitors. So that -- that is -- the circumstance here is not a unique one.
///

BY MR. GORDON:
Q In your experience, is it typical for companies to fund research directed against competitors that are not disclosed in the -- in the --
MS. CONLIN: Objection --
Q -- publications?
MS. CONLIN: -- it calls for speculation, and it assumes facts not in evidence.
THE WITNESS: I -- I mean, I think the only comment I can make is that I think increasingly journals are very careful to get disclosures.
BY MR. GORDON:
Q So you think that would be unusual or rare?
A By current standards, practice.
Q And current in this context goes back how far? Five years? Ten years? Twenty years?
A I would say it's been increasing strategic -- it probably started some decades ago.
Q Well, back in 2012, 2013, would that be part of the current era in your view?
A I think certainly a disclosure was looked at. It was undoubtedly requested.
MR. GORDON: I'll show you Exhibit 19. This was -- this was previously marked as Albrecht

Exhibit 31.
(The aforementioned document was marked Exhibit 19 for identification by the reporter.)
BY MR. GORDON:
Q My first question is, Have you seen this before today?
A You asked if I've seen it before?
Q Yes.
A I don't think so.
Q Okay. And the first thing I want to draw your attention to the title of this email, which is "publication factory continues."
Have you ever described the research and publishing work that you've done as a publication factory?
A I don't think so.
Q Have you ever known anyone to do that, describe the scientific -- scientific research that they're conducting as being something from a publication factory?
A I'm not sure. Certainly people talk about some labs that pour out the papers, but whether the term "factory" idea used or not --
Q Okay. Let's look at the -- the -- who

it's -- who this from and who it's to. The date is July 9, 2010. It's from Mark Albrecht at Augustine Biomedical to Mike Reed, Dr. Reed at Northumbria, Dr. Paul McGovern. And the cc goes to Scott Augustine, Augustine Biomedical; Andrea Lydel [phonetic], Augustine Biomedical; Keith Leland at Augustine Biomedical; R. Humboldt [phonetic] at Augustine Biomedical; and Christopher Nachtsheim. You received it, so...

Do you see that?

A Yes, I do.

Q And then if you read the text, it says (reading):

"Paul and Mike, at this point we have three completed manuscripts that are ready to be submitted for publication that you are both authors on."

And he describes them. And he says (reading):

"I've already sent you both articles 1 and 2" -- "both of the articles, 1 and 2. Article 3 is a new one and arguably the best of the three.

"When I'm in the U.K. next week, I would like to plan a time for us to get together, agree on reviews, and submit these articles at appropriate times."

I -- I know this is the first time you've seen this.

But does this give you any cause for any kind of concern that the published literature out there on which you're relying was -- was being written by Augustine's employee and submitted to authors and with carbon copies to Augustine and several other Augustine Biomedical employees?

A Well, I -- what I don't know is the --

MS. CONLIN: Are you representing these are all the same studies that Dr. Samet has submitted in his report? Because I don't think 2 and 3 are. So I just want to make sure.

MR. GORDON: It's not his title. The title's changed. And I don't think Number 2 was ever published.

THE WITNESS: This is --

MS. CONLIN: I'm going to object to the premise of your question.

///

BY MR. GORDON:

Q Well, Dr. Samet, if -- if the evidence shows in the sworn testimony of Dr. Reed, Dr. McGovern, Dr. Legg, and Mr. Albrecht that Albrecht was involved in all of the published studies, that Augustine was being copied on drafts and involved in this, these were being -- these were coming out of Augustine Biomedical with carbon copies going to Scott Augustine and everyone else, does that give you any cause for concern about the validity or the integrity of these studies?

MS. CONLIN: And, again, I'm going to object to the premise of the question as misstating the record.

THE WITNESS: But I think McGovern, Reed, in particular as authors, have responsibility as authors. And I don't know their role.

My reading of these papers is the work was done, I think, in all the cases in the U.K. So presumably they were there.

All authors have responsibility for the data quality and the integrity of the representation of the findings in the manuscript.

So I -- there are more parties here, and I can't speculate further based on what you have

said. I understand that Albrecht is here at this point working for Augustine when this email was sent.

Q Dr. Samet, do you believe today that mumps and measles and rubella vaccines causes autism?

A I've been thinking why you're asking me the question. The answer is no.

Q The answer is no?

A Do I think it causes autism?

Q Yes.

A No.

Q Okay. In fact, pretty much the consensus in the entire medical community is that MMR vaccines do not cause autism; correct?

A Yes.

Q But there was a period of time when a publication came out written and published in The Lancet and authored by several U.K. doctors' observational study that drew the conclusion that MMR caused autism; correct?

A It's a little bit more complicated if you're referring to the original The Lancet paper by Wakefield and others.

Q I am.

You're familiar with it?

A Correct.
Q That had a pretty big impact on vaccination rates worldwide, didn't it?
A In some places, it had an impact.
Q And even today, it continues to have an impact on --
A Unfortunately.
Q And from your familiarity, I assume you -- you know that at the time the publication was -- came out in The Lancet, Dr. Wake -- Dr. Wakefield, A, had a consulting agreement with plaintiff's lawyers who were trying -- who were preparing to bring lawsuits against the vaccine maker -- makers; and, B, had obtained patents on technology that he contended was a safer way of vaccinating for MMR that eliminated the risk of autism.
Doctor, were you familiar with those?
MS. CONLIN: I'm going to object --
THE WITNESS: I'm familiar with Wakefield.
MS. CONLIN: I'm going to object on relevance.
You can answer.
BY MR. GORDON:
Q And -- and you're -- you know that all his

co-authors were unaware of that connection.
Do you know that?
A As I said, I'm fully aware of the Wakefield --
Q Well, I mean, is -- is that consistent with what you understand?
A The paper was retracted -- retracted and the authors disavowed.
Q Now, that paper had gone through peer review, hadn't it?
A That's peer reviewed publication.
Q Lancet is one of the probably top three medical journals in the world; right?
A It's an important journal.
Q Okay. That paper went through peer review. Wakefield's authors -- co-authors didn't know that he was -- had a lucrative consulting contract with plaintiff's lawyers and patents for -- for a potentially competing product for MMR, and they didn't know that he cooked the data, did they?
A I think they were not aware of what he had done with the data.
Q And neither were the reviewer -- the peer reviewers of Lancet; right?
A No.

Q And Lancet didn't withdraw the article for several years until an investigative journalist in England uncovered all the connections between Wakefield and the plaintiff's lawyers and his patents and demonstrated that he had fabricated data.
Is that part of story as you understand it?
A I've read those articles.
Q Do you have any reason to think that The Lancet independently pulled its -- pulled that article or withdrew it, having nothing to do with the work of that -- the investigative journalists?
A Questions were raised about that report for a long -- a long time. And what tipped Lancet over, perhaps it was those papers. But I think eventually the literature were then clarified.
Q Peer reviewers can only review what's submitted to them?
A By definition.
Q They -- unless the -- an author submits raw data, peer reviewers have to take the representations of -- and they even submitted -- a paper submitted for publication regarding the data and the data analyses as -- as having been accurately, with integrity, with honesty, and with objectivity; right?
A And they would look for indications of

deviations from standard practices or a lack of -- a lack of validity. Sometimes such things are identified at the peer review process.
Q Well, and in the case of the Wakefield, et al., paper, nobody caught any of those issues for quite a while after -- after publication, right, including the peer reviewers?
A Correct.
Q You would agree that peer review in and of itself is not a magic wand that guarantees that whatever is coming out of even the most prestigious journalist is objective, accurate, no errors, no hidden agendas; right?
A Well, a peer review is a -- a -- one of the points of checks on what is in manuscript and the appropriateness of the analysis findings and maybe looks at the data and how the authors are published. It's a multi -- multifaceted process. Then, of course, the journals themselves, the publications.
MR. GORDON: Could we take a quick break.
MS. CONLIN: Sure.
MR. GORDON: I'm segueing to a related but slightly different discussion now.
THE VIDEOGRAPHER: The time is 4:35 p.m. We are off the record.

(A brief recess was taken.)

MS. CONLIN: I've been informed that there's about two and a half hours left.

Dr. Samet announced his departure from the USC today, which is -- caused a number of disruptions to his schedule for today.

Granted has afforded the courtesy of regrouping at a different point in time, because I will have a drive. There's some things that need to be explained and updates based on the examination today and the way things are characterized.

But we will endeavor to get a date that works for Dr. Samet in sufficient time in advance of the August 16 deadline.

And I don't know if you have anything to add, Mr. Gordon.

MR. GORDON: No.

MS. CONLIN: Okay. That's it.

MR. GORDON: Other than -- I agree.

(The deposition proceedings were adjourned at 4:44 p.m.)

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STATE OF CALIFORNIA)
) ss.
COUNTY OF LOS ANGELES)

I, JONATHAN SAMET, M.D., having appeared for my deposition on July 11, 2017, do this date state that I have read the foregoing deposition and that I have made any corrections, additions, or deletions that I was desirous of making in order to render the within transcript true and correct.

IN WITNESS WHEREOF, I have hereunto subscribed my name this day of , 2017.

_____
JONATHAN SAMET, M.D.

DEPONENT'S CHANGES OR CORRECTIONS

Note: If you are adding to your testimony, print the exact words you want to add. If you are deleting from your testimony, print the exact words you want to delete. Specify with "add" or "delete" and sign this form.

DEPOSITION OF: JONATHAN SAMET, M.D.
CASE: IN RE BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION
DATE OF DEPOSITION: JULY 11, 2017

PAGE	LINE	CHANGE/ADD/DELETE

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Deponent's Signature Date _____

PAGE	LINE	CHANGE/ADD/DELETE

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Deponent's Signature Date _____

CERTIFICATE OF REPORTER

I, DORIEN SAITO, CSR 12568, CLR, a certified Shorthand reporter in and for the State of California, County of Los Angeles, do hereby certify;

That JONATHAN SAMET, M.D., the witness named in the foregoing deposition, was, before the commencement of the deposition, duly administered an oath in accordance with CCP 2094;

That said deposition was taken down in stenograph writing by me and thereafter transcribed Into typewriting under my direction.

That before completion of the deposition, review of the transcript [ ] was [ ] was not requested. If requested any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am neither counsel for nor related to any party to said action, nor in any way interested in the outcome thereof.

Dated this 14th day of July, 2017.

_____

CERTIFIED SHORTHAND REPORTER
IN AND FOR THE COUNTY OF
LOS ANGELES, STATE OF CALIFORNIA

U

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation,	)	MDL No. 15-2666 (JNE/FLN)
	)	VOLUME II
	)	PAGES 211-324

VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.

LOS ANGELES, CALIFORNIA

TUESDAY, AUGUST 8, 2017

JOB NO. 128394

DORIEN SAITO, CSR 12568, CLR

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation,) MDL No. 15-2666 (JNE/FLN)

Videotaped deposition of JONATHAN SAMET, M.D., taken on behalf of Defendants, at 2001 North Soto Street, 3rd Floor, Los Angeles, California 90032, commencing at 8:36 a.m., Tuesday, August 8, 2017, before Dorien Saito, CSR 12568, CLR.

APPEARANCES:

FOR PLAINTIFFS:

CIRESI CONLIN
By: JAN CONLIN, Attorney at Law
By: MICHAEL SACCHET, Attorney at Law
225 South 6th Street
Minneapolis, Minnesota 55402

FOR DEFENDANTS:
BLACKWELL BURKE
By: COREY GORDON, Attorney at Law
431 South Seventh Street
Minneapolis, Minnesota 55415

ALSO PRESENT:

JORDAN LEADS, Videographer
MORDECAI BOONE

INDEX

WITNESS:

INFORMATION REQUESTED:

(NONE)

QUESTIONS INSTRUCTED NOT TO ANSWER:

(NONE)

EXHIBITS:

INDEX
(Continued)

EXHIBITS:

I N D E X
(Continued)

E X H I B I T S :

I N D E X
(Continued)

E X H I B I T S : (Previously marked)

LOS ANGELES, CALIFORNIA; TUESDAY, AUGUST 8, 2017
8:36 A.M.
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THE VIDEOGRAPHER: This is the start of tape labelled Number 1 of the videotaped deposition of Dr. Jonathan Samet in re Bair Hugger Forced Air Warming Products Liability Litigation in the United States District Court, District of Minnesota, Case Number 152666 JNE/FLN.

This deposition is being held at 2001 North Soto Street, Los Angeles, California, on Tuesday, August 8 of 2017 at approximately 8:36 a.m.

My name is Jordan Leads from TSG Reporting, Incorporated, and I am the legal video specialist.

The court reporter is Dorien Saito in association with TSG Reporting.

Will counsel please introduce yourselves.

MR. GORDON: Corey Gordon on behalf of the defendants.

MS. CONLIN: Jan Conlin on behalf of the plaintiffs. With me here today is Mike Sacchet.

MR. GORDON: Also -- also here with me

today is Mordecai Boone from the 3M office of legal counsel.

THE VIDEOGRAPHER: All right. Thank you.

Would the court reporter please swear in the witness.

THE REPORTER: Would you raise your right hand.

THE WITNESS: (Complies.)

THE REPORTER: Do you so state under penalty of perjury that the testimony you shall give in your deposition shall be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes.

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JONATHAN SAMET, M.D.,
having been duly administered an oath in accordance with CCP 2094, was examined and testified as follows:

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EXAMINATION

BY MR. GORDON:

Q Good morning, Dr. Samet.

We -- we met about a month ago when we started your deposition.

And I guess the first thing I want to find out

is, Have you reviewed any materials since we last met on July 11?
A I've refreshed my memory concerning materials that I have looked at in the past. But with regard to absolute new materials, no.
Q Okay. So you didn't do any additional research in between July and --
A No, I did not.
Q -- now?
A No.
Q And you weren't -- you weren't given any additional published materials?
A No. I simply reviewed materials I had on hand.
Q I'm sorry? Did --
A I reviewed materials I already had on hand.
Q Okay.
MR. GORDON: And -- and we discussed this a little bit last time. But some of the materials that you listed on your Exhibit C, if I recall correctly, of your report, which we marked as Samet Exhibit 1. I'll give you a copy of it again just to refresh your recollection.
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(The aforementioned document was previously marked Exhibit 1 for identification by the reporter.)
BY MR. GORDON:
Q But some of those materials were ones that -- well, strike that.
All of the materials on Exhibit C in your report were materials that you had available to you prior to when you rendered your decision -- your -- your opinion on March 30; correct?
A That's right. And then there was the additional report by Augustine that was --
Q Okay. And there -- you know, I don't -- I don't want to spend a lot of time plowing old ground.
But in addition to that Augustine publication, you, I think, testified that you had read the expert reports of Holford, Wenzel, Borak. And I --
A That --
Q And I can't remember -- I apologize.
A Right. I'm not sure I can remember.
I -- I will add, actually, have read the -- now the deposition of both Drs. Holford and Borak which were, I think, obtained in the interim between last month and -- and the -- that -- completion of the deposition today.

Q Okay. And other than the depositions of Dr. Holford and Dr. Borak, have you read any other deposition --
A No.
Q -- since July 11?
Okay. And I can't remember.
Had you -- do you recall if you had read the expert opinion of Dr. Michael Mont?
A Offhand, I don't remember, no.
Q Okay. And, again, I don't want to replow old ground. But just -- I want to -- and -- and just so the record is clear. We talked about it before.
MR. GORDON: I want to mark somewhere -- I'm showing you Exhibit 20.
(The aforementioned document was marked Exhibit 20 for identification by the reporter.)
BY MR. GORDON:
Q And ask you if this is the Augustine paper that you said you reviewed.
A That's correct.
Q And you had reviewed that initially sometime in between the time you rendered your original opinion in this case and when you were deposed on July 11; correct?

A That's -- that's right. My understanding is the paper was published in -- in the interim following the preparation of my expert report.
Q And since July 11, you've -- you've gone back and rereviewed this paper; is that right?
A Well, I've -- I've refamiliarized myself with this and other materials.
Q Did you review any other materials in connection with the -- Exhibit 20?
A Other materials specifically, no.
Q Okay. And nothing about any of the hospitals that were involved or any testimony of Dr. Augustine or anything like that?
A No, I have not.
Q Okay. We'll -- we'll come back to that.
You -- and -- and correct me if I'm wrong. But you have not -- it was not listed on your Exhibit C, the deposition of Dr. Augustine.
So as of March 30, you had not read Dr. Augustine's deposition?
A Not -- not that I recall, no.
Q Have you -- and have you read it subsequently?
A No.
Q Okay. All right. I want to step back and -- we'll pull back about 50,000 feet and just talk about

the -- the scientific process that -- that you have employed in -- in this case.

You -- as epidemiologist, you follow certain objective approaches to the -- the materials that you deal with; right? That was a poor -- that was a poor question.

There -- there's -- there's a -- there's a -- there is a methodology that you, as an epidemiologist, follow in order to arrive at conclusions or opinions about causal relationships; is that correct?

A Well, I guess I would say that my review of the materials reflects not only my training in epidemiologist, but in medicine, my broader understanding of the -- the lung, of air, of movement of particles in air, things that I've worked on in my research.

So, yes, I -- I interpret the epidemiological evidence, but I try and put it in the broader context of biology, clinical path, and physiology, and so on.

Q And -- and I -- and I was asking kind of a big picture question.

That's generally how you approach issues of epidemiology and -- and -- and health-related outcomes; right?

A Yeah.

Q You just don't look at an epidemiological study. You try to look at other lines of evidence; right?

A Right. I guess I would -- if you'll excuse me, I would probably rephrase things and say that I approach questions that are relevant to public health, population health, and that epidemiology is one of the research methodologies used to generate evidence that is relevant to public health.

Q In the past, you have been critical of those who contend that epidemiological studies are prone to generating false positives; is that correct?

A I've been involved in some statements concerning -- I would say sort of general comments about epidemiology and the validity of results and how they may be subject to any number of problems, including, quote, "false positives."

MR. GORDON: Let me show you what's been marked as Exhibit 21 just to kind of tee this -- tee this up, and we'll plow through it.

The aforementioned document was marked Exhibit 21 for identification by the reporter.)

BY MR. GORDON:

Q This is -- this is a paper -- let's say a

commentary that you co-authored in 200- --

MS. CONLIN: -9.

BY MR. GORDON:

Q -- -9; is that right? 200- -- yeah, 2009.

A Correct.

Q Okay. And this was something that you and your -- and all -- and the other authors wrote in response to a publication that was simplistic -- and I realize I'm being very simplistic. This was essentially taking the position that observations by the epidemiological studies are fraught with false positives.

A This was written in response to several -- several papers that posed this sort of too strong generalization in the view of the author -- co-authors and myself that there's a generic problem with false positives, correct.

Q And you -- and correct me if I'm wrong. But you -- part of your opinion is based on your conclusion that the McGovern paper does not represent a false positive; is that correct?

A Well, the McGovern paper is certainly part of the evidence that I considered. And to the extent that the P value is less than .05, that's a helpful indication that the results are not arrived by chance

alone.

And then of course since the McGovern paper, there's been a second report that essentially corroborates the -- the findings in other hospitals.

Q You're talking about Exhibit -- the Augustine publication?

A Yes, I am. Yes.

Q So -- and -- and I -- so specifically my question with McGovern is, Your opinion is predicated in -- at least in part on the -- your determination that the McGovern findings were not -- do not represent false pos- -- a false positive --

A That's --

Q -- is that correct?

A That's correct, essentially.

Q And you -- have you similarly concluded that the Augustine publication is not based on a false -- or does -- is -- is not a false positive?

A Well, again, yes. And with two papers that corroborate each other, I think the likelihood that both are, quote, "false positives" diminishes.

And there's -- you know with -- P value is an assessment of the role of chance. There are other ways to generate false positives. But with two papers with quite -- quite similar findings, I think the

strength of evidence from the epidemiological side has -- has grown.

Q Okay. And I -- I want to go back to Exhibit 21, your -- your commentary on a -- on a paper about --

Who is the main author on that?

A Bafeda [phonetic].

Q Bafeda.

-- Bafeda's paper on false positives. And I want to -- and I -- you know I understand this paper was written generally, so I want to understand if some of the principles that you articulated here are principles that you believe you have applied in coming to the conclusions and opinions that you offer in this case.

For example, on -- on the first page in the middle paragraph -- or the middle column, you say (reading):

"It is well-known that observational epidemiological studies may be affected by various biases that can impair their validity and that are generally not present in experimental investigations."

You -- you still agree with that statement, don't you?

A It's a reasonable statement, yes.

Q And you were -- and that was something you were considering when you evaluated both the McGovern paper and then the -- the Augustine paper; is that correct?

A That's correct.

Q Okay. And you go on to say that (reading):

"Critical scrutiny of epidemiological studies covering all potential sources and mechanisms of biasness" -- or -- "biases is indispensable."

You still agree with that?

A Yes, I would.

Q So is that the appropriate --

Would -- would -- would you say that that's the approach you used here in re- -- reviewing the -- the epidemiological component of the McGovern paper and the Augustine paper? In other words, that -- that you critically scrutinized them and covered all potential sources and mechanisms of bias?

MS. CONLIN: Well, I'm going to object to the form of the question. This report is based on McGovern. He indicated that he has reviewed the Augustine paper subsequent to his opinions in the case. And you've got a premise in the question

that his opinion is based on both.

THE WITNESS: Sorry. Can you restate the question.

BY MR. GORDON:

Q When you reviewed the McGovern paper -- we'll start with that one -- you -- you considered that a critical scrutiny of it covering all potential sources and mechanisms of bias was essential -- or -- excuse me -- indispensable; right?

A Well, that -- that's a statement here. I mean, I think in my expert report I review potential limitations of the McGovern report and particularly around the issue of confounding and do describe why I do not consider the results to be attributable to confounding.

Q And, again, I don't want to plow a lot of the -- the ground we did in July.

But the -- the confounders that you considered in your critical scrutiny of the McGovern paper were limited to what was disclosed in that paper; right?

MS. CONLIN: Objection; it misstates his testimony.

BY MR. GORDON:

Q And if it does, that's -- that -- please tell me what I'm missing.

A Well, I mean, first off, they were potential confounders. Not all factors are necessarily confounders. They were potential confounders. And I considered the possibility that they were confounding in association -- observed with the use of the Bair Hugger device.

Q But the confounding factor -- the potential -- excuse me. Strike that.

The potential confounding factors you considered were only those that were actually disclosed in the publication itself; correct?

A I think if the comment -- of course I considered the potential confounders. Discussed those that were highlighted in the publication.

If the question is, rather, quote, "unknown confounders," I'm not sure what -- what they might be given the close temporal alignment of the Bair Hugger and the conductive warming time periods.

Q Well, again -- again, I don't want to -- we spent a lot of time on this in -- in July.

But there were -- we were talking -- there were a number of factors that we discussed that you -- that were not disclosed in the paper that I -- and correct me if I'm wrong -- that your testimony indicated that you had not been aware of or considered

prior to rendering your -- your opinion on March 30. For example, the -- a MSSA screening or repair of a malfunctioning laminar flow ventilation system in one of the operating theaters, things like that.

Do -- do you recall that --

A I'm --

Q -- generally?

A I'm -- I'm aware that there were other changes being made within the healthcare system to address surgical site infections.

Q And you had not focused -- or -- strike that.

Prior to rendering your decision on March 30, you had not considered those factors insofar as they were not mentioned in the McGovern paper itself?

A Right. Yeah. No. I think I said on my expert report what factors I explicitly considered.

Q And one of the things that the McGovern paper mentioned was that they did not factor in all patient-specific considerations.

Do you recall that? We -- we can go to the paper, but one of them was fitness for surgery. Diabetes was another one. A couple things like that. Do you recall that?

A Well, the analysis was conducted at the level of contrast and what happened, two time periods and

not -- not around specific individuals.

Q Okay. Would you agree with me that in -- in -- in doing a proper observational study on deep joint infection rates, that -- that it's important to consider patient-specific factors to -- to determine if the two cohorts you're looking at have any potential confounders in the -- the patient demographics?

A I think that one of strengths of the McGovern study was, in fact, the close proximal temporal alignment of the two time periods. I mean, it seems somewhat unlikely that over the course of a transition period of two months there would be major changes in patient demographics that would affect -- affect risk.

MR. GORDON: Let me show you Exhibit 22. This is a 1989 publication -- or -- excuse me -- a 1990 publication by Gordon, et al., and the senior author is William Jarvis.

(The aforementioned document was marked Exhibit 22 for identification by the reporter.)

BY MR. GORDON:

Q Have you seen this paper before?

A No, I have not.

Q And you -- you know that -- that Dr. Jarvis is one of the experts retained by plaintiffs in this case?

A Yes.

Q Have you -- had you read his report?

A I did read Dr. Jarvis's report.

Q And you consider him an expert in infectious diseases; correct?

A He seems very well-qualified, yes.

Q And you consider him an expert in investigation of -- of hosp- -- nosocomial infections specifically; right?

A He has -- he has a very likely record of such research.

Q Okay. And, you know, again in the interest of time, I don't expect you to study this in -- in detail, but I -- and certainly feel free to read the -- whatever you want. But the abstract, you know, might be the quickest.

But in this case, Dr. Jarvis and his colleagues did an epidemiological investigation to look at an apparently unusual infection rate -- knee and -- knee joint infection rates in a couple of hospitals in Atlanta.

And one of the factors they looked at was the ASA status of the patients. And they concluded that having an ASA class equal to or greater than 3 was itself an independent risk factor statistically --

was associated in a statistically significant way with an increased risk of deep joint infection.

And, again, you can read that part if -- if you want. But my point -- my -- my question is -- is really -- it's not fair. I'll give you a chance to read it.

(Witness reviewing document.)

THE WITNESS: So if I can comment. I mean, just to read one sentence. (Reading):

"Logistic regression analyses identified being a patient operated on by surgeon X with an ASA class great than 3 as the only significant independent risk factor for total knee arthroplasty-associated surgical wound infections are equals."

So it was actually the combination of the surgeon and ASA class greater than 3 that operated together. In other words, there was a synergism in here which is shown in Table 4, in fact. So they don't find an independent effect of ASA Class 3. It's a combination of surgeon and ASA class.

BY MR. GORDON:

Q And -- and thank you for educating me on that.

So in this -- and -- and I understand you just briefly skimmed it, but you -- but the --

After doing their -- their various analyses, they concluded that the -- what distinguished one group of patients from another was having Dr. X as their surgeon and an ASA score of 3 or greater, is that right, though that combination of factors increased their -- significantly increased their risk of deep joint infection?

A At least as described in this particular outbreak, yes.

Q Right.

Now, there's no way that they would have been able to make that conclusion if they hadn't looked at surgeon-specific factors or ASA scores; right?

A Well, for the purposes of this particular investigation, yes.

Q In other words, if -- if they had come in and they had -- and there's a list of all the things they -- they looked at. It starts on -- the second page, bottom paragraph, on the right hand, medical records and the study of patients reviewed. It lists a whole bunch of different things they -- they looked at.

Do you see that?

A Yes, I do.

Q Okay. If they had only looked at everything in that list except segregating out the procedures by surgeon and the ASA scores, based on the analysis that -- that I understand you only had a brief chance to review, they wouldn't have been able to conclude that there was any -- any significant risk factor going on that would allow them to make -- to distinguish why -- why one person would get a deep joint infection and one -- and another wouldn't?

MS. CONLIN: I'm going to object. I think it's kind of unfair. He hasn't had a chance to read this whole study. In the interest of time, I think he's trying to move along. But if you want to ask him specifics, you've got to give him an opportunity to read it, Mr. Gordon.

MR. GORDON: That's fair.

Q And, Doctor -- Doctor, if you do want to read it, that's fine. I think -- I think my question is -- is a little bit more general and -- but, please, if you -- if you feel otherwise, take the time.

They concluded it was the combination of a particular surgeon and -- and the surgeon's ASA scores.

There's no way they could have drawn that conclusion if they hadn't gotten -- gathered the data on the different surgeons and the -- and the different

ASA scores and then incorporated that into their analysis; right?

MS. CONLIN: The same objection.

THE WITNESS: Well, just looking at the paper rather cursorily, of course, I mean, it's a -- essentially an investigation of a cluster of infections at a particular -- at two hospitals that experienced a sharp increase.

I'm just reading the first paragraph of the methods. And so it's an effort to understand what was driving essentially an outbreak of -- of infections at these two institutions.

So they were focusing on trying to understand what -- what factors, whether patient physician or otherwise, might have driven a particular cluster of infections as described here.

BY MR. GORDON:

Q And just -- as, I mean, just a general proposition, if you don't look at patient-specific factors and you don't look at surgeon-specific factors, you can't determine whether patient- and/or surgeon-specific factors are playing a role in infection rates; right?

MS. CONLIN: Objection as to form.

THE WITNESS: Well, again, I would actually say that this paper is not about infection rates. This is about the individual determinates of -- of risks.

The individual was -- the -- the individual infection case was defined as any patient that had a surgical wound infection after total knee arthroplasty.

So, again, this was not about what was driving the rates but what was driving the risk for specific individuals.

BY MR. GORDON:

Q Well, let's go back to your Exhibit 21 and see if I'm being obtuse.

In -- on the second page of the paper -- or the commentary, you say -- and this is at the bottom of this middle column under confounding. You say (reading):

"Epidemiologists are well aware of the potential for confounding, to introduce noncausal associations, and generally take steps in the design and analyses" -- "analysis phases of research to address confounding."

A I'm sorry. Could you --

Q It's under confounding in the middle -- in the page -- the --
MS. CONLIN: 18- --
(Witness turning to page.)
THE WITNESS: Oh, I see it. Okay.
BY MR. GORDON:
Q Internal page 1810.
A Okay.
Q I'll read it again. (Reading):
"Epidemiologists are well aware of the potential for confounding, to introduce noncausal associations, and generally take steps in the design and analysis phases of research to address confounding."
Right?
A Yes.
Q And you still agree with that; right?
A Yes.
Q Okay. If you'll now turn to page -- internal page 1812.
(Witness turning to page.)
BY MR. GORDON:
Q The bottom of the very last paragraph there in the conclusion section, you say -- you and your

colleagues say (reading):
"It is the responsibility of epidemiologists to design and conduct studies in a way that makes them capable of assisting public health and clinical decisions. We also believe that an evaluation of epidemiologic findings based on a balanced weighing of potentials for false-positive and false-negative biases along with other considerations of strengths and weaknesses within the framework of all other pertinent scientific evidence can and does produce valid scientific knowledge essential to public health actions and to advancement of science."
You still agree with that, don't you?
A I'm just finding it. Yes, I do.
MS. CONLIN: It's on --
THE WITNESS: Confounding. Okay.
BY MR. GORDON:
Q And -- and here you're talking about public health actions and -- and the advancement of science.
Would -- would you agree that this statement as a general proposition is -- is applicable for

offering expert testimony in -- in court cases as well?
A I think it's a valid statement of interpretation of epidemiological evaluation of epidemiological evidence.
Q Okay. And -- and I don't want to focus specifically on -- on the -- Dr. Jarvis's study in Exhibit 22.
But just generally when it comes to doing the -- conducting studies and evaluating studies if you're doing an epidemiological study, one of the ways an epidemiologist tries to do it right, do it in the scientifically appropriate way is to consider potential confounders and design the -- the study to, you know, allow for analysis of the impact, if any, of potential confounders; right?
A Well, I wouldn't -- I would not describe the full approach of confounding as simplistically as you did. There's consideration on the design side, consideration on the analysis side, and there's also judgment and interpretation of -- of the potential for confounding to lead to an association.
Q But starting point for -- for considerations is that you have to actually consider something; right?
A (No audible response.)
Q Whether something is or is not a potential

confounder or could be a potential confounder, you have to consider it at some point along in -- in the process in order to -- to make that determination; right?
A Well, at -- you know, again, at -- at the point of interpreting McGovern, specifically I was not involved in the design or analysis and left with interpreting the published manuscript and other related materials that I've seen.
Q Well, based on you -- what is published in the paper in addition to the discussions of the antibiotics and the thromboprophylaxis, which we spent some time on in your last deposition, is there anything in there that indicates that they -- they gave any consideration to surgeon-specific factors?
A Again, I -- as I -- as I said, I think the strength of the design is the fact that the time period between the Bair Hugger and Hot Dog intervals is rather brief. So I'm not sure what surgeon-specific factors might have changed.
And, again, in my expert report, I allude to the strength of the estimate and the potential for confounding to be so strong as to generate an association of an odds ratio of 3.8.
Q And when we went through the analysis the last time -- and, again, I don't want to spend a lot of time

on this, but I want to -- want you to recall the discussion of Professor Holford's calculation of the odds ratio based on Dr. Reed's testimony that there should have been one additional deep joint infection in each of the cohorts that were considered and Dr. Holford's calculation came up with an odds ratio of 2.86.

Do you recall that?

A I recall that, yes.

Q And I read your deposition again last night, and I'm pretty sure that -- what your answer is, but I -- it was -- it was -- there's just enough of a question in my mind that I want to ask.

Do you have any reason to quarrel with Dr. Holford's analysis of that 2.86 odds -- odds ratio?

A Well, I think it's a straight -- the calculation of the odds ratio itself is a rather straightforward matter, I think.

The basis for Dr. Reed's comment that the data set might have this error in it, I'm not sure. I'm a little bit -- I don't know the basis for that comment.

But the computation of adding one to each of the appropriate cells is a rather simplistic matter.

Q Well, do you have any basis for questioning

Dr. Reed's testimony that there should have been one additional infection added to --

A Well --

Q -- each cohort?

A Of course I -- I don't. I simply don't know what the basis for his suggestion is.

Q Okay. Do you need the -- the basis to factor in his sworn testimony on that point into arriving at your opinions?

A Well, I will only give a more general response. That when one suggests that there's an error in the database, it's usually with some specific justification that a correction is made.

Q All right. And the reason I'm asking you this is because you -- you once again mentioned a 3.8 odds ratio and -- and you discussed that earlier in your deposition.

Based on Dr. Reed's testimony and Dr. Holford's recalculation, the odds ratio at most is -- was 2.86; correct?

MS. CONLIN: I'm going to object --

THE WITNESS: Yeah.

MS. CONLIN: -- to the form of the question.

THE WITNESS: If that's the specific

number. I'd have to go look to verify that it's 2.86. But it's around -- it's around that value.

BY MR. GORDON:

Q All right. So in -- in holding the opinions that you hold today and are prepared to offer in court, is your opinion based on your assumption that the McGovern study stands for the proposition that -- that there is a 3.86 odds -- odds ratio or something else?

A Well, the -- relying on the published peer reviewed paper, the odds ratio that stands in the literature is 3.8.

Q And my question, though, is, Is that what you're relying on in the opinions you hold as you sit here today?

A Well, as stated in my expert report, I addressed the issue of the potential for confounding to lead to an estimate of 3.8.

Again, I think if -- if one were to say could the estimate be 2.8 based on Reed's comment, I think the same issue still stands around the potential for confounding to generate a relative risk that is roughly triple the -- I'm sorry. Yeah -- tripling the risk for deep joint infection.

Q So whether it's 2.8 or 3.8, it doesn't in any way impact your opinions?

A You know, again, the point is that you have to postulate a set of uncontrolled confounding factors that could lead to such strong association.

Q Okay. And just looking at Exhibit 22, one -- there was a -- a -- at least a statistically significant association with a particular surgeon and a particular -- and a particular cohort of patients, their -- their ASA class; right?

A Well, the paper shows a particular positive interaction between being -- having higher ASA class and having been operated on by a particular surgeon, yes.

Q And neither the surgeon-specific factors or patient-specific factors were -- were considered in the McGovern paper; correct?

MS. CONLIN: Asked and answered.

THE WITNESS: Well, again, I -- I think I commented. The same institution in a very short temporal separation of the two time periods.

BY MR. GORDON:

Q Let's go to the Augustine paper, if you would. Was that Exhibit --

MS. CONLIN: 20.

BY MR. GORDON:

Q 20. And your -- based on what Dr. Augustine

stated in that published paper, would you agree that his protocol called for basing his analysis on one year of hip and knee deep joint infection data when Bair -- when forced-air warming was used at each -- at each institution, a sixty-day wash-out period when they switched from forced-air warming to conductive blankets, and then between six and twenty-four months of -- of conductive blanket deep joint infection data within the institution?

A That would seem to be what the second paragraph of the materials and methods says.

Q Okay. So -- and I want to break that down.

So the -- the first part of that protocol as you understood it when you read the paper was that whatever the data were by looking at each of these institutions, the -- the data should be one year of Bair Hugger forced-air warming, sixty days where there was a crossover and data was not collected, and then whatever the next six to twenty-four months were of conductive blanket blankets in that particular population; right? That's -- that's 1?

A That's correct.

Q Okay. And the second -- a second part of the protocol as you understood it was they were to look at both knee and hip deep joint infection data; right?

A It's my understanding, yes.

Q Now, when -- let's take a look at the second page of the Augustine paper.

(Witness turning to page.)

BY MR. GORDON:

Q And under Center 1, it lists conductive fabric and forced-air and number developing infections and number not developing infections, right, in Table 1?

A Yes.

Q Okay. So just -- I want to look at the numbers slightly differently than they're presented in this -- in this -- in this table.

Would you agree that the -- these data would indicate that there were -- during the conductive fabric period there were two infections in a total of 677 procedures?

A Correct.

Q And there were six --

And during the forced-air period, there were six infections in a total of 388; is that correct?

A Yes.

Q And your understanding based on the protocol is what that is saying is that these data would indicate that there was -- there were 388 knee and hip procedures in the forced-air warming year of which six

resulted in -- in deep joint infections; right?

A Yes.

Q A two-month wash-out period when the data were not collected.

And that the 677 procedures of conductive blanket or conductive fabric, that took place -- those took place sixty days after switching from the forced-air warming to the conductive blanket?

A You mean -- you mean the data acquisition period?

Q Yes.

A Yes.

Q Okay. And just to be clear. Your understanding was that those 677 procedures included hips and knees?

A Let me just verify that on the --

(Witness reviewing document.)

THE WITNESS: I'm looking because they are using the term "periprosthetic joint infection." It talks about the McGovern study of hips and knees, but I'm actually looking at the -- the first sentence of the protocol, it says (reading):

"Periprosthetic joint infection rates."

Just looking for a place where it might specifically say hips and knees. It seems implicit since it's in reference to --

Well, I guess the first sentence of the discussion. (Reading):

"This is a multicenter observation of outcome study investigating the possible relationship between FAW and PJI in hip and knee total joint replacement."

So that would seem to be where he specified what the outcome is rather than in the method study. Okay.

BY MR. GORDON:

Q But at least when you -- you read it the first time and then reviewed it again in -- in between our last meeting and today, you understood that these -- these data were based on both hip and knee and the -- the data collection periods that we discussed; right?

A Correct.

MR. GORDON: Let me show you Exhibit 23. This is a single page bearing Bates Number RMC000025. I will represent to you that this is a document produced in discovery in this litigation by -- pursuant to subpoena to Ridgeview Medical Center.

(The aforementioned document was marked Exhibit 23 for identification by the reporter.)

BY MR. GORDON:

Q And the first question I'll ask is, Have you ever seen this before?

A I don't think I have, no.

Q Okay. And if you'll look at the first slide there, it says (reading):

"Conductive fabric warming data site reduction in joint implant infections..."

It discusses what Ridgeview Medical Center is. Then what I want to direct you attention to are -- are numbers. The first bullet point there, it says (reading):

"The total knee arthroplasty infection rate in 2006, 1.55 percent. Warming standard forced-air, 388 cases."

Did I read that correctly?

A Yes.

Q And then the next bullet point there, it says (reading):

"Total knee arthroplasty infection rate 2008 to 2009, 0.29 percent. Warming standard conductive fabric, 677 cases."

Did I read that correctly?

A Yes.

Q Okay. And if you read the text below, it says (reading):

"Here we have anecdotal evidence of reduced orthopedic knee implant infections. It's from the main hospital, the regional healthcare network in Minnesota, that has switched to air-free conductive fabric warming for the last three years."

I'm going to skip a little bit down. Well -- (reading):

"Though not using laminar flow, this hospital is known for its high quality and is doing many things to reduce surgical infection as evidenced in its Number 1 ranking overall care among Minnesota hospitals by MyHealthcare -- MyHealthcare.com research.

"Nonetheless, it is interesting to note that when they were using forced-air warming, their total knee arthroplasty infection rate was 1.55 percent. When they transitioned to conductive fabric

warming three years ago, their infection rate dropped to 0.29 percent for 2008 to 2009.

"I recognize that this is anecdotal and does not constitute scientific proof of a linkage between waste heat and wound infection, but it is interesting.

"Anytime infection rates drop by over 80 percent, it should get your attention. And a 0.8 infection rate is world class by any standard."

Did I read that correctly?

A Yes.

Q Would you agree with me that what this is describing is, first of all, just knee infections?

MS. CONLIN: Objection; lack of foundation.

THE WITNESS: Well, what it makes reference to in what appears to be a slide is total knee arthroplasty infection rate.

BY MR. GORDON:

Q There -- is there anything in here that would suggest to you that the infection rates that are -- that are being referenced here are -- include the deep joint infections for hip arthroplasty?

MS. CONLIN: The same objection.

THE WITNESS: No. The page you provided refers to the total knee arthroplasty.

BY MR. GORDON:

Q All right. And you would agree that the -- the number for 2006 that's listed here, 388, that's exactly the number in the Augustine paper for Center Number 1 for the forced-air period in Table 1, right, 388 cases?

A Well, both numbers are 388.

Q Okay. And the same thing with the conductive fabric for 2008, 2009, the total number of cases listed is 677.

That's the total number of cases in Table 1 for Center 1; correct?

A Both tables are 677.

MR. GORDON: I'll show you what's been marked as Exhibit 24 -- wait. I'm sorry. It's the wrong -- I give you the wrong one. No. No. I gave you the right one. I grabbed the wrong one for Jan. Let me find it.

What's -- what's -- there was another exhibit number.

MS. CONLIN: 55 -- 35. Augustine 35.

MR. GORDON: August 35. I know I had

three copies of that.
You know what, Doctor, I'm going to -- let me withdraw that because I don't -- I don't want to take the time to find it. I know I have three copies.
But I'm going to mark a different exhibit as Exhibit 24. Coincidentally, it was previously marked as McGovern 24. And this is a document bearing Albrecht 0002079 through -2086.
(The aforementioned document was marked Exhibit 24 for identification by the reporter.)
BY MR. GORDON:
Q I will represent to you that this document was produced by Mark Albrecht pursuant to a subpoena in this litigation.
I'm assuming you have not had an opportunity to see this before.
A No, I have not.
Q And --
MS. CONLIN: No. He -- this is -- he's got a list in --
MR. GORDON: I'm sorry. Jan is -- I -- I didn't mean --
Q This was a McGovern exhibit, and you --

A Oh, I see.
Q That was one of the -- one of the exhibits you would have --
A Okay.
Q -- had available to you; right?
A Okay.
Q And I --
A Right. Too many things to remember.
Q Sure. And I apologize.
If you'll turn to page 3 of Exhibit 24 and look at that Table 1 --
(Witness turning to page.)
BY MR. GORDON:
Q -- and compare it to Table 1 in the Augustine paper for Center 1.
Would you agree with me that those numbers are identical?
A Yes, they are.
Q Okay. Now I want you to turn back to -- to the second page of -- of Samet Exhibit 24, which is actually the first cover page of this draft article.
A I'm sorry. Which page?
MS. CONLIN: Bates 2080.
THE WITNESS: I got that. But the first page.

BY MR. GORDON:
Q Yeah. And I just -- I wanted to direct your attention to the -- you know, the -- the top where it says (reading):
"Forced-air warming linked to periprosthetic total joint replacement infections."
Do you see that?
A Yes, I do.
Q And per the authors of this, Scott D. Augustine, M.D., and Paul D McGovern, M.D.
Do you see that?
A Yes, I do.
Q Would it surprise you to learn that Dr. Augustine had drafted this without any knowledge of Dr. McGovern and then asked him -- and then sent it to Dr. McGovern and asked him to agree to be listed as a co-author?
A I really can't comment on that communication. I mean, I --
Q I'm just asking you if -- if you -- I want you to assume for the sake -- for the sake of my question that that is the case.
Would that surprise you? Would that seem to you --

A Yeah. Under the hypothetical assumption that McGovern had not been involved in the preparation of the --
Q I'm -- let me be very specific. For the purpose of my question, I would like you to assume that Dr. McGovern knew absolutely nothing about this, that Dr. Augustine drafted this with the statistical analysis done by Mr. Albrecht, and that then only after it was drafted Dr. McGovern -- or -- excuse me -- Dr. Augustine sent a copy to Dr. McGovern and asked him if he would like to have his name on this paper. For the purpose of my question, please assume those facts.
Would that surprise you?
A I'm not going on use the word "surprise." It would not be the usual way that a co-author is involved in a publication.
Q Okay. Now, let me show you Exhibit 25. Single document bearing Bates Number RMC000039. And, again, I will represent to you that this was a document produced pursuant to a subpoena by Ridgeview Medical Center. And the title of this document is "RMC Total Joint Infection Rates 2006 Through 2009."
(The aforementioned document was marked Exhibit 25 for identification by the reporter.)

BY MR. GORDON:
Q Do you see that?
A Yes, I do.
Q Okay. And if you look at 2006 under knee, it shows a rate of 1.55 percent based on six out of 388 procedures; is that correct?
A That's correct.
Q And that's the exact same number that we saw for 2006 in --
What did we mark this exhibit as?
MS. CONLIN: I think that was 23.
MR. GORDON: Exhibit 23?
MS. CONLIN: Let me just double-check.
MR. GORDON: The PowerPoint slides.
MS. CONLIN: Yeah.
MR. SACCHET: 23.
MS. CONLIN: 23.
BY MR. GORDON:
Q Would you agree that the number for 2006 for knees as reflected on Exhibit 25 is the same number that we see on Exhibit 23 for 2006?
A Sorry. Just --
Q It's that one (indicating).
A Yes.
Q Okay. It's also the same number that we see

on Table 1 for the forced-air period in the Augustine paper; correct?
A That's correct.
Q Okay. And if you go back to Exhibit 25, the total number of knee procedures for 2008 and 2009 is 777, right, on Exhibit 25? Excuse me. 677.
A I'm sorry. Which number, again, are you --
Q If you combine the number of cases in 2008 and 2009 for knees on Exhibit 25, the total is 677; right?
A Correct.
Q And there were two infections in that -- in those two years of those 677 knee cases; right?
A In -- yes, in Exhibit 25.
Q On Exhibit 25.
And if you do the math, two divided by 677, that would come out to 0.29; right?
A I haven't done the math. But that figure is repeated over and over again, so I'll accept it.
Q It's the same -- and so the number -- again, the numbers we see on -- for knees on Exhibit 25 for 2008 and 2009, they correspond exactly to what's shown in Exhibit 23 for knees for 2008, 2009; correct?
A Correct.
Q And they correspond exactly to the numbers listed in the Augustine paper for the conductive fabric

period for Center 1; right?
A Correct.
Q But there are no years given in the Augustine paper; right?
A That's correct.
Q So reading this -- reading the Augustine paper and based on his protocol of one year of forced-air, sixty days wash-out, and then the -- the period of conductive fabric, the -- your understanding when you read this was for Center 1, the data represented an infection rate of 1.5 percent for hip and knee infections over one year, and sixty days after the transition from forced-air to conductive fabric, there were two hip and knee infections out of a total of 677 procedures; right?
A Right. Again, I -- I commented on what's in the materials, the methods where it says periprosthetic joint infection is specified, and then commented on what was said at the start. But certainly that would lead the reader to view -- to consider that the paper refers to hip and knee.
Q Right.
And a continuous period of data collection with the exception of that sixty-day wash-out period; right?

A Correct.
Q There's nothing in the paper, the published Augustine paper, to indicate that there was a one-year gap in the data for Center 1; right?
A Correct.
Q Now, if you'll look at Exhibit 25.
(Witness turning to exhibit.)
BY MR. GORDON:
Q You see that for the year 2007 under knees alone there were 344 procedures and no infections; correct?
A I'm sorry. 2007, the 344 cases, zero infections.
Q And I will -- if -- if -- for purposes of my question I'd like you to assume that Ridgeview continued to use the Bair Hugger in its procedures in 2007. For purposes of my question assume that to be the case.
Would you agree that if you -- if you followed the protocol that that Dr. Augustine used in his paper of one-year followed by sixty-day wash-out period during the transition and then the data collection for whatever period of time, six to twenty-four months, of conductive fabric, that the -- the data that he would have had to have used if he was just using knees would

have been 0 percent infections for the forced-air warming period versus .29 percent during the conductive fabric period?

MS. CONLIN: Objection as to form.

THE WITNESS: So I don't know whether 2007 was a -- was -- was used that year under --

BY MR. GORDON:

Q I understand that. I'm asking you to assume that.

A -- under your proposed assumption that forced-air warming was used. According to his protocol of how the time series was devised, it would have been the forced-air warming year of the transition and then the further data collection under with conductive warming.

Q And just for -- for purposes of this, I just want you to focus on the knees on Exhibit 25.

You would agree that if -- if the Augustine protocol was followed just looking at knees, and if I'm -- if -- I want you to assume that the Bair Hugger was used throughout 2007 -- then the data would have been reported as 0 percent infection for forced-air versus the .29 for knees -- for conductive?

MS. CONLIN: Objection as to form, it assumes facts not in evidence.

THE WITNESS: Again, only under that -- under that hypothetical assumption if this protocol were -- your forced-air warming followed by the transition period followed by conductive warming, the 2007 would have been the comparison year.

BY MR. GORDON:

Q Okay. Now, again, assuming -- I want you to assume for purposes of my question that they used the Bair Hugger in 2006 and 2007.

If we looked only at hips, would you agree that the overall infection rate for hips actually went up when they switched from forced-air warming to conductive fabric?

MS. CONLIN: The same objection. It assumes facts not in evidence.

THE WITNESS: I -- I mean, again, under the assumption, which I have no information about as to when forced-air warming was used, .67 and 1.04 corresponding to 2006 and 2007 are numbers that are lower than 1.1 and 1.33 corresponding to 2008 and '9.

BY MR. GORDON:

Q So those -- the numbers actually would have gone up. I'm not -- I'm not suggesting the statistic

was given, just the raw numbers actually went up for hips alone when they were switching from Bair Hugger to conductive fabric?

A Well, the example speaks for itself.

MS. CONLIN: Yeah.

BY MR. GORDON:

Q And, in fact, if you look at the combined numbers of knee and hip, would you agree that if you used Dr. Augustine's protocol of one year -- the -- the final year of forced-air warming, sixty-day wash-out, and then whatever period -- additional period of conductive fabric, and was -- again, my -- for the purposes of my question assuming that this was -- that Ridgeview continued to use the Bair Hugger in 2006 to 2007, the one-year fabric -- excuse me -- the one-year Bair Hugger period would have had an combined infection rate of .37 based on Exhibit 25; right?

A Apparently.

MS. CONLIN: The same objection.

THE WITNESS: I mean, I haven't checked the math, but the figure listed here is .37 percent.

BY MR. GORDON:

Q And based on this, that number would go up in the first conductive -- excuse me. Yeah -- in the

first conductive fabric year of 2008, it would go up from .37 to .76; right?

A Well, the figure for 2008, as you say, is .76, yes.

Q And 2009 would go down to .41; right?

A That's the figure for 2009.

Q And I don't want to have to spend a lot of time doing deep math here.

But would you agree with me that if you looked at 2007, the combined rates, and compared it -- compared it to a combined rate of 2008 and 2009, the absolute raw numbers would not show a decrease in infections as between the Bair Hugger and the conductive fabric? Is that right?

A I think the question is if you compare the combined rate for 2007 with what the combined rate would have -- would be for 2008 and 2009, the figure for 2007 would be lower.

Q And I'm not suggesting again statistically stating.

But just as an absolute number, it would be slightly lower; right?

A The percentage would be lower, yes.

Q And, again, if Augustine was following his purported protocol in this publication, then the

Center 1 using both hip and knee and using his protocol would have -- not only would not have shown an improvement in joint infection rates by switching to conductive fabric, it would have shown a slight detriment; right?

MS. CONLIN: The same objection.

THE WITNESS: I mean, again, under the assumptions that 2007 was the forced -- appropriate forced-air warming year. According to the protocol, the findings would be different using 2007 compared to 2006, if -- that's I think the question.

BY MR. GORDON:

Q Was there anything in his protocol that would suggest that it would be appropriate under any circumstances to skip a -- to just skip over a year?

A I don't have the protocol in front of me. This -- if, in fact, this relates to -- what is in Exhibit 25 relates to the results provided in the published paper for Center 1 and the numbers aligned. But the years aren't given. The center description is simply -- simply Center Number 1. I -- the -- the -- omission of 2007, if indeed it were a forced-air wanting year, it would not correspond to what's stated in the published papers.

Q So if these numbers on Exhibit 25 from Ridgeview Medical Center accurately reflect what was happening at Ridgeway Medical Center and if Center 1 in Augustine papers -- Augustine's paper is, in fact, Ridgeview Medical Center, would you agree with me that Dr. Augustine's paper did not follow his own protocol? Let's start with that question.

A Well, if -- I mean, with -- with the two assumptions as to the nature of Center 1, its connection to Ridgeview and so on, and with the assumption the 2007 was a forced-air warming year, then the numbers provided in Table 1 of Exhibit 20 would appear to deviate from the protocol as stated in the materials and -- and methods.

Q And I'm not going to ask you to do complicated calculations right now, but if -- if you can tell me just by eyeballing it.

If you were to substitute the numbers from Exhibit 25 for combined joint infection rates for '07 versus '08 and '09 for Center 1, would that have do you think an impact on the multicenter pooled results?

A I'm sorry. What am I substituting?

Q If I -- if instead of the numbers that Dr. Augustine used for Center 1 you substituted the combined numbers shown on Exhibit 25 and used 2007 as

the Bair Hugger year in 2008 and '9 as the conductive fabric year -- year or period, would that have any impact on the multicenter pooled results?

A Well, if, just to be clear, point -- the .37 figure were used, if I -- if I understand correctly, I mean, the -- the estimate would be lower. I mean, the -- the direction in which the multicenter pulled us, it would be pulled -- it would be downward.

Q And, again, I know it would probably take a -- take some time to do an analysis.

But when you say downward, you mean it would -- it would tend to show that the impact of changing from forced-air warming to conductive fabric had less of an association with the decrease in surgical site --

A Yes, the infection --

Q -- infections?

A The first mode would be reduced.

Q Can you tell if it would be reduced to a point where it would no longer be statistically significant?

A I can't make that calculation.

Q Okay. Understood.

And so for purposes of my question, I'd like you to assume that Center 1 as reflected in Dr. Augustine's paper is Ridgeview Medical Center. I

would also like you to -- to assume that the data set forth in Exhibit 25 accurately reflects the infection rates for Ridgeway Medical Center during the periods reflected. And I'd also like you to assume that if Dr. Augustine's protocol -- well, strike that. I would also like you to assume that Bair Hugger was used at Ridgeview Medical Center in both 2006 and 2007. And, finally, the data that Dr. Augustine used in his paper for Center 1 covered 2006 through 2009 omitting 2000 -- the data from 2007.

If all those things are in fact true, would you agree with me that the conclusions of Dr. Augustine's published paper would not be something that will support your opinions?

MS. CONLIN: Objection --

THE WITNESS: Oh.

MS. CONLIN: -- as to form. And I think as stated previously as the court went in the report, in the Augustine paper.

Subject to that, you may answer.

THE WITNESS: Okay. I mean, again, I understand why you're offering the assumptions. And I think I answered the question.

The -- under those assumptions, the estimate for Center 1 would not be 4.59 but some

other figure much lower, and it would have some effect on the pooled estimate.

And -- and beyond that, I can't say how it would influence my overall judgment of the paper. But I think if one were to do the calculations, Center Number 2 would stand with its very strong risk, Center Number 3 has a relatively low risk, and the evidence from this paper would be less convincing than it is in its published form.

BY MR. GORDON:

Q Okay. How many cases are listed for Center 2 in total?

A Center 2, a total of four cases.

Q I mean, the four infections -- the total -- the total end would be 218 plus 171 plus 4; is that right?

A 218 plus 171 plus 4.

Q And that would be 393; is that right?

A Correct.

Q Now, the total number of cases for -- listed on Exhibit 1 for -- or Table 1 for forced-air would be -- in the multicenter pooled results would be 929 plus 16; right?

A I'm sorry. Can you say that again.

Q If you add the total number of infections and the total number not developing infections for the multicenter pooled results for forced-air, that would be 16 plus 929 or 944; right?

MS. CONLIN: 945.

THE WITNESS: 945.

BY MR. GORDON:

Q 945.

Is that right?

A 16 plus 929 is 945.

Q Okay. Now, if you go back to Center 1, the total number of forced-air cases listed is 388; right?

A Correct.

Q If you look at Exhibit 25, if you used the combined hip and knee and the total number for 2007, that would be 537; correct?

A Correct.

Q So that would add 155 cases to the total number of forced-air cases; right?

A I'm sorry. Say your -- give me your math again. Why don't we just accept that your --

Q Well, my point is simply that Center 1 if -- I want you to assume that as reported by Dr. Augustine he's only reporting hip -- he's only -- excuse me -- he's only reporting knee infections without saying so.

Okay?

And if you used the combined numbers aside from the difference in infection rates, the absolute total number attributable to Center 1 goes up; right?

A It is combined infection rates.

Q And without -- I understand without doing the -- the numbers, you can't give -- give an exact number.

But you agree that the -- the overall percentage rate of combined infection rates at Ridgeview from the 2007 period versus 2008, 2009 the -- the actual number actually goes slightly up; right?

A I'm sorry. I think I lost you on that one.

MS. CONLIN: I am too.

BY MR. GORDON:

Q Okay. Again, the -- the combined number for 2007 at Ridgeview was .37. And if you add 2008 and 2009 for the combined number -- we haven't done the math, but we -- we --

You agree that it's going to be something a little bit higher than .37; right?

MS. CONLIN: Objection; form.

THE WITNESS: It will be higher then if you average .4 for 1 point, yes, clearly it would be higher.

BY MR. GORDON:

Q And in the paper, Dr. Augustine reports that the difference in Center 1 that -- that forced-air warming is not only not a little bit lower than conductive fabric, but it's 4.59 times as high; right?

A Well, the odds ratio is 4.5 million.

Q And if you take that out and add all the, you know, numbers in, is it -- do you have -- are you able to tell me whether the difference you see in the 393 cases reported for Center 2 would result in there being a statistically significant odds ratio for the multicenter pooled results?

MS. CONLIN: Objection; asked and answered.

THE WITNESS: I'm not sure I can answer the question as you asked it. I think I commented before that -- again, that substituting the combined data for what is in the table would lead to a reduction in the odds ratio for Center 1, and that would correspondingly reduce any pool in the three studies.

BY MR. GORDON:

Q And given the relative size of the -- of the -- of Center 1 and Center 2, would you agree that having Center 1 change from having a 4.59 odds ratio to

a -- an odds ratio of slightly under 1.0, the overall impact on the multicenter pooled result would be to -- to render any apparent difference between forced-air warming and conductive fabric not statistically significant?

MS. CONLIN: Objection as to form, asked and answered.

THE WITNESS: Yeah. Again, I haven't done the calculations. Clearly the sample size using the combined hip and knee for Center 1 is much larger than that of Center 2, and there would be a substantial impact on the pooled estimate.

BY MR. GORDON:

Q And several times in your -- in the July deposition and again today you -- you referenced the Augustine paper as something that provides further support for the -- the findings in the McGovern paper; right?

A Yes, I have.

Q Okay. If you assume everything I've asked you to assume about the Ridgeview data on Exhibit 25 and -- and what Center 1 actually is, would -- would you still think that the Augustine paper provides support for the conclusions in the McGovern paper?

A Oh, it -- probably state that it would raise

uncertainty about the -- the results as reported in the Augustine paper.

Q And you would agree that a peer reviewer only gets to review what is presented to him or her; right?

A A peer reviewer typically sees what is in the publication and any supplemental materials, correct.

Q And, again, assuming that my -- what I -- all the facts that I've asked you to assume are correct, no -- a peer reviewer wouldn't have had any way of knowing that the numbers that Dr. Automatic reported in his paper are inaccurate, would he or she?

MS. CONLIN: It assumes facts not in evidence.

You may answer.

THE WITNESS: I mean, a peer reviewer would not have access. Assuming that Exhibit 25 is relevant to the Augustine paper, would not have access to this information.

BY MR. GORDON:

Q Now, if you had been asked to be a peer reviewer for the Augustine paper and presented with the paper as drafted, as published but were also provided with the information that I've just gone through with you and the assumptions that I've asked you to make, would you, as a peer reviewer, say, "Eh, no problem.

Let the paper go in as" -- "as drafted"?

A Well, I think if I received a paper to peer review with additional material questioning the data, I would simply refer the matter back to the editor.

Q Wouldn't -- Doctor, wouldn't you agree that if my assumptions are accurate, that this Augustine paper is misleading?

A I -- again, as I -- as I said, if the assumptions with regard to Center 1 as presented, as represented is true, it certainly raises questions about the findings as provided in the published paper.

Q And my -- my question is predicated on the assumption. If I'm all wrong, then obviously what you answer to this hypothetical is -- is of no import.

But if I'm correct, if -- if the assumptions that I've asked you to make prove to be substantiated by the evidence, would you agree that what Dr. Augustine wrote is misleading?

A Again, as I said, if the assumptions are correct, it would raise a great deal of uncertainty about the findings as presented here because they would not be based on the whole data set or perhaps according to the protocol of the correct data set.

Q Whether -- whether it would be misleading or not, you can't say?

A Well, the findings would be different from what is in the report.

Q And the report is -- reports a 78 percent reduction in implant infections; right?

A That's correct.

Q And you -- you previously testified that you -- based on that 3.8 odds ratio, that that translates to about a 74 percent reduction in infections; is that right?

A I haven't done the calculations. But, yes, approximately.

Q Well, it's essentially --

A Yeah.

Q -- the same thing as -- as attributable risk, isn't it?

A Yes.

Q So whatever you said the attributable risks was in the report.

78 and 74 are pretty close to each other; right?

A They are.

Q So if the Augustine paper used -- used the data as I'm suggesting -- no. I --

For purposes of my question, I want you to assume than instead of using the combined data from

Ridgeview and do -- and following the protocol by using 2007 and comparing it to 2008 and 2009, Dr. Augustine picked out the data only for knees, used 2006, ignored 2007, and then used 2008 and '9, and entered those into the -- the calculus for the multicenter pooled results.

Would you agree with me that that would be a -- an improper methodological approach to presenting data?

MS. CONLIN: The same objection.

THE WITNESS: Well, again, under the assumptions you've given, it would suggest that he did not follow his protocol as described, albeit briefly, in the materials and methods.

BY MR. GORDON:

Q And throughout your career, you've been troubled by the misuse of data and science by the tobacco industry, haven't you?

A At times, yes.

Q Yeah.

Well, have there any times you've been -- you haven't been troubled by the misuse --

A Well --

Q -- of the science by the tobacco --

A -- I -- I think perhaps I was referring to science in those matters and the like, yes.

Q Any day with a y in it, basically; right?

If -- if what I'm telling you is true, if the -- if the evidence I'm providing you is true that the -- the owner of the company that is competing, is trying to sell a competitive product to forced-air warming is using data in the way I've -- I've described it to you, does -- does that give you any kind of similar concerns about the way -- similar to the way the tobacco industry manipulated and misused data?

A Well, I -- I would simply say that, you know, under the assumptions that you have listed, again if Augustine deviated from the protocol and perhaps to have a high odds ratio in the Center Number 1, that would certainly represent a deviation from appropriate scientific practice.

Q Would that bother you?

A If that were the case, it would bother me, yes.

MR. GORDON: Could we take a quick break?

THE WITNESS: Yeah. Absolutely. So why don't we -- how --

THE VIDEOGRAPHER: The time is 9:58 a.m. We are off the record.

(A brief recess was taken.)

THE VIDEOGRAPHER: We are back on the

record. The time is 10:07 a.m.

BY MR. GORDON:

Q Dr. Samet, if you were to disregard the McGovern -- the observational component of the McGovern paper and disregard the Augustine paper, just assume for the purposes of my question those two things either did not exist or you concluded for whatever reason that they're just -- they're just not reliable, would you still be of the opinion that the Bair Hugger is a substantial contributing cause to deep joint infections?

A Well, I mean, I think in my expert report, I lay out the mechanistic basis for the plausibility of the association that is observed in -- particularly in the McGovern paper at the time of my expert report.

The McGovern paper supplies the only estimate of the risk associated for deep joint infection associated with use of the forced-air warming Bair Hugger device. So absent the quantitative estimate from that paper, it would be -- while there would be a quite plausible mechanistic basis for increased risk, there would not been asked an association in -- in the real world.

Q So without McGovern and without the -- excuse me. I want to be clear. I'm not talking about the

bubble component of McGovern. I'm talking about only the observational component and now the Augustine.

Without those two things, would you agree that you could -- would no longer be in a position to opine that the Bair Hugger was a substantial contributing cause -- factor causing joint infections?

A Well, again, the basis on which the --

(Mr. Boone joins the deposition proceeding.)

THE WITNESS: -- magnitude of the association was considered in my report comes from the McGovern estimate. And absent that estimate, I would not have another way to construct a quantitative estimate.

BY MR. GORDON:

Q And without a way to construct a quantitative estimate, you couldn't say whether something was or was not a substantial contributing cause; right?

A I would not be able to judge the quantitative magnitude of the association.

Q In fact, based on the -- what you describe as the mechanistic basis -- information -- mechanistic data, all that does is -- is lead to a possibility, not a probability; right?

A Well, again, I think -- I wouldn't use the

word "possibility." "Probability." Those considerations which I addressed extensively in my expert report related to the biological plausibility and the coherence of the total body of evidence.

Q And my -- and that's -- again, assume -- disregard the -- the observational component of McGovern, disregard Augustine. All you have are those mechanistic data or studies.

Would you be -- would you be offering the opinion as an epidemiologist to a reasonable degree of medical certainty that the Bair Hugger is a substantial contributing cause to joint infections?

A To restate what I think I said is, I would have no basis for describing the quantitative magnitude of the risk which underlies the -- the use of the word "substantial" as we discussed previously.

Q So you wouldn't be offering that -- that opinion; correct?

A I wouldn't have the basis for doing so.

Q Okay. Let's talk about the mechanistic component that you have discussed.

What -- what -- you know, sort of a 50,000-foot view. What -- what are you -- what are you describing as -- as the mechanistic evidence?

A Well, I think it's laid out in my expert

report, and I think there's a figure that describes that -- the conceptualization of the mechanisms. And there's a fair amount of text about how the components of that figure are supported.

And I also used the sufficient cause model to describe how the Bair Hugger device configured into -- essentially creating an additional cause of -- of deep joint infection, adding to those that already -- that exist absent Bair Hugger.

Q All right. Are -- are you talking about the figures on page 8 of your report?

MS. CONLIN: It's right here (indicating).

THE WITNESS: That's a sufficient cause piece of -- of it. And then there's the additional figure which is on page 14.

BY MR. GORDON:

Q All right. I just want to ask a quick question or two about Figure 2B on page 8. Then -- then we'll go to the other one.

There you -- you have three different pie charts; right?

A In 2B, correct.

Q And then you have Cause 1 and Cause 2 and Cause 3; right?

A They're so labeled.

Q Why is surgery part of the pie in a Cause 2 but not in Cause 3?

A Well, these are, again, hypothetical examples and simply to show that -- that the use of Bair Hugger creates additional cause. It could be that surgery could be included there.

Again, as I state clearly in the text that this is a hypothetical and simply intended to show how the Bair Hugger could lead to the introduction of a causal mechanism that is otherwise not present. It couldn't -- again, this was simply a hypothetical.

Q Okay. Well, now let's turn to page 14 in your Figure 3. And you have two arrows coming off of the Bair Hugger device, one being to disturb unidirectional flow and other one being microbial contamination of the surgical field; correct?

A Right.

Q And between those, you have arrows going either way.

What -- what does that mean?

A Well, it's -- it -- it is intended to show that the -- there's this interaction, if you will, between the two, that the Bair Hugger device is elevating the numbers of microbes through introduction

of organisms, that the device itself is heat, the flow of air disrupts unidirectional flow. And those two together lead to this increased dose and increased number of infectious organisms reaching the surgical site.

Q Okay. So regardless of whether it's through the mechanism of disturbing unidirectional flow or microbial contamination of the surgical field or an interaction between those two factors, the ultimate mech- -- mechanistic way that you're -- you're positing that the Bair Hugger would cause the joint infections would be through an increased dose of infectious organisms; right?

A Well, the path to increased risk would be through an increased dose, correct.

Q And by increased dose of infectious organisms, you're talking about viable pathogenic bacteria; right?

A An increased number of colony-forming organisms, yes.

Q So for shorthand, let's call them CFUs. All right?

A Okay.

Q So if what -- through whatever mechanism the Bair Hugger increases CFUs, that's what your positing as the mechanistic part of your opinion; right?

A I'm suggesting that the pathway -- and I think it's laid out with the arrows from Bair Hugger -- to increased risk is mediated through an increased number of infectious organisms reaching the surgical site.

Q To conclude that the Bair Hugger is capable of increasing the dose of infectious organisms, you need some evidence that it actually increases the number of CFUs arriving at the surgical site, right, wouldn't you?

A Well, I think I -- again, it's laid out in my report how the literature supports both -- both pieces, the disturbance of unidirectional flow, increased numbers of infectious organisms in -- in the air.

And then, of course, there is this -- and also there's demonstration of increased numbers of particles, again a surrogate for what is in the air reaching the surgical site.

I think there's substantial evidence that's supporting each of the pieces of the diagram.

Q Okay. Is there any evidence that supports the actual increase in the dose of infectious organisms?

A I'm not sure what -- what constitutes such evidence. Again, I'd lay out how the pieces of this

diagram are supported by the evidence reviewed in the report.

Q Okay. Well, one of the pieces of evidence you reviewed in the report is --

MR. GORDON: I'm going to show you Exhibit 26. That's the Stocks [phonetic] paper.

(The aforementioned document was marked Exhibit 26 for identification by the reporter.)

BY MR. GORDON:

Q That was something you specifically reviewed and cited; correct?

A Yes, I did.

MS. CONLIN: What number is this?

MR. GORDON: I think it's 26.

MS. CONLIN: Okay.

BY MR. GORDON:

Q And in -- you cite the -- Exhibit 26 for the proposition that particles are a valid surrogate for CFUs; right?

A It's one of the papers I cited, yes.

Q How did -- how did --

The researchers in Exhibit 26, how did they conclude that particles were a valid surrogate for CFUs?

A Well, they models outcomes relative to CFUs in relationship to particle counts.

Q How did they go about modeling the CFUs?

A They used a regression model.

Q Well, they just make up numbers or --

A I'm sorry. What -- what is the question?

Q Well, they measured CFUs, didn't they? They weren't just going into a computer and typing out random numbers?

A Is the question, What is the underlying data set?

Q Yeah.

They -- they -- they measured colony-forming units; correct?

A In this paper, they measured particles and colony-forming units, correct.

Q And they did an analysis to see how the -- the number of particles that they measured compared to the number of viable bacteria that they were able to culture out through different active and passive measuring techniques; correct?

A It's -- I think you more or less described what the protocol was.

Q So they -- but in order to even come to this conclusion, they actually set up something to measure

particles -- measure CFUs; right?

A Well, they were interested in looking at what predicted the biolog- -- the bacterial population reaching the surgical sites.

Q Do you recall what the size particles were that correlated in the Stocks paper, Exhibit 26, with the CFUs?

A The fraction that was statistically significant in models was the 10-micron or greater.

Q And the studies that you were referring to earlier that you say demonstrate that Bair Hugger increases a number of particles, what size particles does -- has the Bair Hugger been shown to increase?

A Well, let me --

I'm sorry. Could you restate the question.

Q What size particles, in -- in your understanding of the literature upon which you're relying, has the Bair -- does the Bair Hugger cause an increase?

A Well, I am not sure. I would have to go back and it look at the literature. So sitting here today, I'm not sure how many studies have actually done size fractionated -- aerodynamic size fractionated measures.

They have measured bacteria at surgical

sites. They have measured particles in the air. I'm not sure how many of those studies have done a -- if any have done this kind of size cuts that are shown here.

Q You -- you said they measure bacteria at surgical sites.

What -- what studies are you talking about?

A I'd have to go back to my report and look at them.

Q Is it your recollection that there were studies that showed that the Bair Huggers significantly increased bacteria at surgical sites?

A I need a moment to look through the report. Excuse me. I'm looking through and refamiliarizing myself on what is here.

(Witness reviewing document.)

THE WITNESS: I think if the question was did I cite, as I look at it, studies specifically on Bair Hugger and organisms reaching the surgical -- the surgical site, there were studies on contamination in the air but not at surgical sites specifically.

Q When you say "contamination," you're talking about bacterial contamination?

A I'm talking about bacterial culture, that's

correct.

Q What studies are those?

A Again, I need a minute to come back and find those.

(Witness reviewing document.)

THE WITNESS: Again, there's a -- one of the studies where the cut -- the counts go up. I just -- sorry. I can't find it right now.

BY MR. GORDON:

Q Your -- but your recollection of the study is it actually found a statistically significant increase in bacteria in the air when the Bair Hugger was --

A Yes.

Q -- turned on?

A I -- it was a study of a forced-air warming device. I'm sorry. I just can't --

Q Well, just -- I know you're on very limited time, so I'm going to just kind of follow through with --

A Okay.

Q -- some other things.

MR. GORDON: Let me show you Exhibit 27.

(The aforementioned document was marked Exhibit 27 for identification by the reporter.)

BY MR. GORDON:

Q This is a paper by Christina, et al., in 2012.

This was listed in Exhibit C as part of your reference materials; correct?

MS. CONLIN: Is this Exhibit 27?

MR. GORDON: Correct.

THE WITNESS: That's correct. It's listed.

BY MR. GORDON:

Q And we -- we -- would you agree with me that this Christina paper, Exhibit 27, actually comes to a different conclusion than the Stocks paper that you actually cite in -- in the text of your opinion? In other words, the Christina, et al., study concluded that there was not a correlation between particles and bacteria in operating theaters for arthroplasty?

A Just give me a moment --

Q Sure.

A -- to look at it.

(Witness reviewing document.)

THE WITNESS: The only -- I'm going to -- this is a rather sparse presentation. There are two points. It says the size cuts are not the same as the Stocks article. They are greater than .5 and greater than 5.

The data are described only as not revealing any statistically significant correlation. So I don't know what the actual values of correlation were, so...

But from what they describe, they did not find a significant correlation with the .5 and the greater than 5-micron cuts.

BY MR. GORDON:

Q Why was it that you chose to sort of specifically reference and discuss the Stocks paper in your expert opinion, but you didn't say anything about the Christina paper?

MS. CONLIN: You mean other than listing it as a reference review?

MR. GORDON: Right.

THE WITNESS: I don't have a particular recollection. I reviewed a great deal of material.

I also mentioned the Darius [phonetic] paper with regard to ventilation, CFUs, and infection rates.

BY MR. GORDON:

Q Well, both the Darius paper and the Stocks paper in your view support the notion that if the Bair Hugger increases particulate counts, that that is an

indication it was -- would likely be increasing bacterial counts; right?
A Well, the general point was that -- that the particle count is a surrogate for -- a useless surrogate indicator of -- I think the presence of the level of CFUs in the air, correct.
Q And -- and the Christina paper that you had available to you and that you reviewed, that actually was contrary to that conclusion; right?
A Well, it's contrary. It's also very uninformative as to actually what was found and what the data are. There's simply -- there's no quantitative information given as to the correlation. It's simply dismissed as not statistically significant.
Q Okay. And -- and -- but you didn't say anything about this contrary study; right?
A It's not directly mentioned in my expert report or cited.
MR. GORDON: Let me show you Exhibit 28. This is a paper by Landrin, et al., from 2005.
(The aforementioned document was marked Exhibit 28 for identification by the reporter.)
///

BY MR. GORDON:
Q This was not something you reviewed; is that correct?
MS. CONLIN: Are you representing that it's not on this list?
MR. GORDON: I don't believe it is, but...
THE WITNESS: That's not on the list.
BY MR. GORDON:
Q And given that it's not on your list, we can conclude that it was something that you did not review; right?
A I don't think I've seen this paper.
Q Did you do any search on your own to find literature that would have cast a different light on the question of whether particles are a valid surrogate for bacterial colony-forming units?
A Well, I think if you look in my expert report, I describe the searches that were undertaken.
Q But -- and does -- can we conclude that search either didn't --
Well, can we conclude that that search did not come up with Exhibit 28?
A Apparent -- apparently not. I mean, you know, again, I will say that searches are of varying

sensitivity in finding the full scope of the literature. But the citations that -- I'm sorry. The search strategies that are used are laid out on page 9.
Q You considered the question of whether particles could be valid surrogates for viable bacteria of colony-forming units to be an important question, didn't you?
A I considered it to be part of the evidence. Considered -- it's laid out in the mechanistic figure.
Q Do you -- are -- are you confident that you did a thorough search for published peer reviewed literature that addressed -- that addresses the issue of whether particles can be a valid surrogate for CFUs?
A I'm not sure what you mean. I mean, I did not carry out a systematic review on the topic, if that's the question.
Q Okay.
MR. GORDON: I'm going to show you what's been marked as Exhibit 29. It's a 2017 paper by Oguz, et al.
(The aforementioned document was marked Exhibit 29 for identification by the reporter.)
///

BY MR. GORDON:
Q And this is not listed on your reference materials; correct?
A No.
Q Have you ever seen this paper before today?
A Not to my knowledge, no.
Q Were you aware from any source that a study had been conducted that compared bacterial counts at the surgical site when a Bair Hugger was used versus when a Hot Dog was used during actual orthopedic surgeries?
A Well, again, the only thing that I can say is that the searches were carried out, the search terms as described. This one may have been published sufficiently close to the time the searches were done that it was not picked up.
Q Okay. Would you agree that an actual study in an OR during actual orthopedic surgeries measuring colony-forming units when the Bair Hugger is on versus when a Hot Dog is on would be a better form of evidence than measuring particles?
A I'm sorry. Let me look at the paper.
Q Sure.
(Witness reviewing document.)
THE WITNESS: Again, this -- just to

comment on the paper, it appears to be a study in which people were assigned to warming with either a Bair Hugger or a Hot Dog device, and measurements were made.

I -- I think the point I was addressing in my mechanistic formulation that's laid out in the diagram had to do with particles and bac- -- bacteria that can cause infection, CFUs.

This is something -- about something different. And I have not read this before, so I would have to take a closer look at it to understand what -- what they did and what they found.

BY MR. GORDON:

Q Fair enough. And, again, in the interest of time, I won't ask you to take the time to look at that since it was something that you've seen before today.

MR. GORDON: I'm going to show you Exhibit 30, previously marked as McGovern Exhibit 6.

(The aforementioned document was marked Exhibit 30 for identification by the reporter.)

BY MR. GORDON:

Q And because it was a McGovern exhibit, does

that mean that you -- this is something you would have read?

A I may have. I actually really don't remember seeing this, sitting here now.

Q Okay.

A Yeah.

Q And I just direct your the conclusions on the front page. It says (reading):

"Use of forced-air warming devices does not increase the bacterial count in the vicinity of the operative field. However, it is noted that the introduction of airborne particles from outside the laminar flow zones, the operative field increases the bacterial count. Many of those which could be pathogens themselves were sterile -- sterile particles that form an itis for pathogen growth."

Do you see that?

A I see the conclusion section, yes.

Q Okay. Then if you would turn to -- the pages aren't numbered -- but the one that has a discussion on it. It's about four or five in from the end.

(Witness turning to page.)

MS. CONLIN: What's the exhibit number on this? 30?

MR. GORDON: Yes.

MS. CONLIN: Okay.

BY MR. GORDON:

Q Do you have the page that has discussion on it?

A Yes, I do.

Q Okay. And the second paragraph there, I'll read it. (Reading):

"The particle counts measured from the four experiments show that when the surgeon enters the vicinity of the operative field, the particle count rise in that zone. This is most marked when the surgeon touches the disinfected skin. This could represent epithelial particle shedding from the patient.

"However, there is no suggestion from these results that turning on the FAW device makes any difference to operative field particle counts. Bacterial sampling from operative field and FAWs have shown that there were very low numbers of skin bacteria found within

these various areas of the operating theater.

"These experiments show no notable increase in either ambient particle count or bacterial count in the vicinity of an operative field when a forced-air device is being used. Low bacterial counts in all experiments are reassuring.

"However, the potential for introduction of airborne particles from outside the laminar flow zones to the operative field is a potential concern. There could be pathogens themselves or sterile particles that form an itis for pathogen growth."

Then it goes on to say (reading):

"Further studies are required to ascertain if there is any relationship between the increase in particle levels seen here and possible increase in pathogens during the operative procedures."

Was this information you considered in drawing your conclusions?

A I actually -- (coughing) excuse me. I don't

recall directly considering this. I would have to relook at it now in terms of a simulation. Clearly this was a simulation, and I'd have to relook at the details.

Q Would it impact your assessment of this to know that this study was originally funded by Augustine?

A I don't have a comment on that.

Q Would it impact your evaluation of this to know that -- well, two of the researchers were Dr. McGovern and Dr. Reed, the same people who were behind the -- part of the McGovern paper that you -- that we talked about?

A Right. My -- my understanding is that they are both well-respected clinicians. And in the case of Reed as a researcher later in the field, I don't have a basis to suspect them from what I had -- the information I have.

Q Would it impact your assessment of this at all that to know that no effort was ever made to publish it?

A Again, I just can't comment on it. I don't know its history.

MS. CONLIN: Why don't you tell him why, Mr. Gordon.

MR. GORDON: Well, we'll let the judge decide why.

Let me show you Exhibit 31, previously marked as Augustine Exhibit 8.

(The aforementioned document was marked Exhibit 31 for identification by the reporter.)

BY MR. GORDON:

Q Have you ever seen this document before?

A This one, no.

Q Okay. I will represent to you that this is a compilation of several experiments performed by Augustine employees in the 2007, 2008 time frame and was produced through a subpoena in this litigation to the Augustine Company.

Given all the research activities that Dr. Augustine and his employees undertook and published with respect to the Bair Hugger, would it surprise -- does it surprise you that they had on five different occasions tried different ways to demonstrate that bacteria was actually coming out of the Bair Hugger and couldn't find -- and couldn't demonstrate that?

MS. CONLIN: Objection; it mischaracterizes the record.

You can answer.

THE WITNESS: I'm -- I'm not sure I can answer given that I've been handed a 29-page document. I don't --

BY MR. GORDON:

Q Fair enough.

A -- know the contents of it.

Q And you've never seen it before?

A I've never seen it before to be able to comment.

Q And, again, one of the -- one of the areas that has troubled you as a scientist throughout your career has been the way that the tobacco industry suppressed unfavorable research; right?

A Well, they -- I'm not sure if it's suppressed. I mean, I think what its concern is, is their efforts to discredit evidence and sometimes to publish, if you will, counterevidence. They -- from the documents, we know they did not publish much of their work in peer reviewed literature. That was not their intent.

Q Well, were you -- have you ever -- strike that.

So a criticism of the tobacco industry for suppressing internal research that was unfavorable to the tobacco industry, that's not part of your

criticisms of the tobacco industry; is that right?

A I'm not sure what you're getting at. I mean, I think it's fair to say that all of us who work in tobacco control understood that the tobacco industry was carrying out research related to its products that may have either given insight into why their cigarettes are so addictive or into their toxicity, and none of this information was generally published. They did publish in the peer review literature.

But I'm not sure what your question is.

I mean, there was, obviously, a concern on the part of all of us -- all of us without knowledge until the documents came out that they harbored secrets, if you will, about the risks of their products and how they enhanced them to create addictiveness.

Q Does it concern -- would it -- strike that.

Would it concern you at all if the evidence demonstrated that Dr. Augustine and his employees were engaged in doing all sorts of research about the Bair Hugger, a competitive product, and published those results that could be construed as demonstrating that the Bair Hugger was unsafe but did not publish and kept secret evidence that the Bair Hugger was safe?

MS. CONLIN: Objection; it assumes facts

not in evidence, and it mischaracterizes the record.

You may answer.

THE WITNESS: I mean, I don't think the only answer -- I mean, I have no knowledge of what Augustine Biomedical or Augustine and his coworkers did or did not -- did or did not do, and so it's -- it's very hard for me to answer the question.

If the suggestion is that only selective results were published, I would have to know what was published and what was not published.

BY MR. GORDON:

Q And for the purposes of my question, I'm just asking you to assume that.

If it turns out that Augustine and his employees published things that made Bair Hugger look bad and anything that exonerated Bair Hugger was not published, is that something that you would find troubling?

MS. CONLIN: The same objection. It assumes facts not in evidence.

THE WITNESS: Again, I think -- if -- if legitimate scientific research being is carried out, the entire body of findings should be

published.

BY MR. GORDON:

Q So the answer to my question is, if that were to be the case, that would be troublesome to you?

MS. CONLIN: The same objection.

THE WITNESS: Again, I said that, you know, open -- science -- scientists publish the full the body of their work.

MR. GORDON: Let me show you what's been marked as Exhibit 32. It's a document bearing Bates Numbers Augustine 3548 through -3551.

(The aforementioned document was marked Exhibit 32 for identification by the reporter.)

BY MR. GORDON:

Q First of all, Dr. Samet, have you ever seen this before?

A No.

Q Were you -- has it ever somehow come to your attention that there was a guide to product liability litigation involving the Bair Hugger?

A I'm sorry. That such a guide exists?

Q Yes.

A I'm not aware of it.

Q Okay. And you see that this has a --

The front page would indicate that it was coming from a group of attorneys; right?

A Well, it's -- it listed it was coming from Kennedy Hodges, LLP. I have no knowledge of authorship.

Q And would it surprise you to learn that Dr. Augustine authored it?

A Again, I have no knowledge of authorship.

Q I understand you have no knowledge.

I'm asking you, If you were to find out that Dr. Augustine was behind this litigation guide, would that surprise you?

MS. CONLIN: Lack of foundation.

THE WITNESS: I -- I have -- I just simply can't answer the question other than I'm not sure if it surprises me or not. Sure, who typically authorizes such documents or what the purpose is, I just don't have a basis for answering the question to say whether I'd be surprised or not.

BY MR. GORDON:

Q If you could turn to page 4 of Exhibit 32.

(Witness turning to page.)

BY MR. GORDON:

Q And under recent research, do you see that

paragraph? The first paragraph there, it says (reading):

"The most dramatic research directly linking Bair Hugger to periprosthetic joint infections (PJIs) was conducted by McGovern -- McGovern, et al., and published in the November 2011 Journal of Bore -- Journal of Bone & Joint Surgery BR," Britain. "This research" -- "this research shows that Bair Hugger FAW is linked to a 3.8 times increase in deep joint infections."

Do you see that?

A Yes, I do.

Q And that's the same 3.8 figure that you used in your report and forms the basis -- formed the basis of your attributable risk assessment; right?

A It's the figure given in McGovern.

Q Now, for purposes of my question, I'd like you to assume that Augustine and his employees were directly involved in the McGovern paper, directly involved in the other papers purporting to show bacterial contamination inside the Bair Hugger or particle distribution or particle increases when the Bair Hugger was turned on, disruption of laminar

airflow, those mechanistic things, that Dr. Augustine and his employees also conducted research that demonstrated that the Bair Hugger didn't actually increase bacteria at the surgical site and never published it, and Dr. Augustine hired a group of plaintiffs' lawyers and drafted this guide to product liability litigation in their name, set up a website ostensibly in the name of the plaintiffs' law firm, sent out the guide to other plaintiffs' law firms in an effort to encourage litigation.

If you -- if all those facts were assumed to be true, is that something that you, as a professional scientist, epidemiologist, public health expert -- is that something that you -- you'd feel comfortable associating yourself with?

MS. CONLIN: I'm going to object to the form of the question both based on the fact that it misstates the record and it misstates the facts and makes assumptions that are not borne out by the evidence in this case.

THE WITNESS: I'm not going to ask you to repeat the question, but...

And, again, I have not seen this document. I do find it difficult, which I think you implied, that an entire body of literature in

this sense has been both created and -- and legitimate investigators like McGovern and Reed somehow were contaminated by a single individual.

So I -- I think that's the -- the scenario that you laid out with your list of assumptions. I really can't comment on it because I don't have the basis for -- for doing so.

But I find it somewhat implausible to think that, you know, legitimate academics with strong records would allow their work to be subverted, if you will.

BY MR. GORDON:

Q It's happened, though, hasn't it, in the past? We talked about Dr. Wakefield [phonetic] and all the other co-authors on his Lancet papers.

A I'm not sure that Dr. Wakefield was a legitimate academic. Unfortunately, his co-authors signed onto that particular paper.

Q By legitimate academics, I was referring to some of the co-authors of Dr. Wakefield's Lancet paper.

A Certainly there were people who had solid reputations who were co-authors on that paper.

MR. GORDON: Let's take a quick break. See if I have --

THE VIDEOGRAPHER: The time is 10:53 a.m.

We are off the record.

(A brief recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 10:56 a.m.

MR. GORDON: Dr. Samet, I have a number of other things I can -- can take time asking you about. But I understand you have a very narrow time window. So out of respect to you and your other commitments, I'm going to pass the witness.

THE WITNESS: Great. Thank you very much.

MS. CONLIN: Thanks.

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EXAMINATION

BY MS. CONLIN:

Q So I just have a couple questions, Doctor.

You are relying in part of on Dr. Jarvis and Dr. El-Ghobashy [phonetic]; is that correct?

MR. GORDON: Object to the form of the question.

THE WITNESS: Yes.

BY MS. CONLIN:

Q Okay. And with respect to this issue of particulates being a proxy for CFUs, were you aware the PJI consensus in 2016 says that there is a correlation

between the two?

MR. GORDON: Object to the form of the question.

THE WITNESS: Yes, I am aware.

BY MS. CONLIN:

Q And you're aware that Dr. Jarvis testified to that as well; correct?

MR. GORDON: The same objection.

THE WITNESS: Yes, I am.

BY MS. CONLIN:

Q Okay. One of the studies that you mentioned in your report, the Moretti [phonetic] study, did that show direct evidence of significant increase in bacteria or CF use in the Bair Hugger?

MR. GORDON: The same objection.

BY MS. CONLIN:

Q I believe it's on page 12 --

A Let me --

Q -- 13 of your report?

A Let me find my report. But that rings a bell, and it's perhaps what I was looking for.

I'm sorry. Page --

Q I think it's 13, Doctor.

(Witness turning to page.)

THE WITNESS: That's correct.

BY MS. CONLIN:
Q Okay. And with respect to Exhibits 30 and 31, Mr. Gordon took you through some documents and asked you if you had -- knew whether they were published or not.
You reviewed Dr. McGovern's testimony in this case; correct?
A Yes, I did.
Q Okay. And do you recall him testifying that the study wasn't well-conducted not controlled and flawed --
MR. GORDON: Object to the form.
BY MS. CONLIN:
Q -- or things to that -- and things to that effect?
A I'm --
MR. GORDON: Object to the form --
THE WITNESS: I'm not sure I --
MR. GORDON: -- of the question.
THE WITNESS: I'm not sure I remember that, but I --
BY MS. CONLIN:
Q Okay.
A -- can go back and remind myself.
Q Okay. Finally, with respect to -- you

testified in your first deposition about Dr. Holford's time trend analysis?
A Yes, I did.
Q Okay. And you -- you mentioned it was simply too small to do any sort of formal analysis.
What did you mean by that?
A I meant a formal time series analysis in which there was an effort to sort of more specifically stratify events over time and see what happened. The data set is too small for that purpose.
Q Okay. And with respect to his chart on the time trend analysis, you understand that he included data from 2007?
A That's right. He included data from 2007 before the surveillance system was fully implement and online in July of 2008.
Q Okay. And did you take --
Do you take issue with that, then?
A Well, it --
MR. GORDON: Object to the form of the question.
THE WITNESS: Well, it -- it means that the initial period that's brought into the averaging is information that is different from what comes later and probably underestimated.

BY MS. CONLIN:
Q Okay. And would that impact his conclusions as set forth in his report?
A It would affect his conclusions that they were sort of two humps of infections. The first one was simply a reflection of the lower period being averaged in with the full surveillance time period.
Q Okay. And Mr. Gordon talked to you about some of the potential confounders as set forth in the Borak and Holford reports, including impact of wound dressings, impact of SSI bundles, and the MSSA screening.
Have you seen any published literature that would suggest that these are, in fact, true confounders as it relates to the results in the McGovern study?
MR. GORDON: Object to the form of the question.
THE WITNESS: I'm not aware that they affect deep joint infection rates.
MS. CONLIN: Thank you. I have no further questions.
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FURTHER EXAMINATION
BY MR. GORDON:
Q Just a quick follow up on Holford. I don't

have it in front of me.
But are -- are you saying that if you were to disregard the data prior to July 2008, that that would flatten out the infection rate curve between July 2008 and when -- whenever the end of the Bair Hugger study period was?
A What I'm suggesting is that if prior to July 2008 when the full surveillance system was implemented if the averaging started there moving forward, the estimate would start at a higher -- higher point. And I can't comment on sort of that dip, as I recall, coming along the middle and then rising again. The -- the curve would look different.
Q Well, specifically with respect to that dip, is there any reason to think that if you lopped off that pre-July 2008 data, that that dip would somehow disappear?
A I would have to look at the timing of the -- that dip versus the window. The curve -- the curve would look different. I can't, sitting here without that in front of me, comment.
MR. GORDON: Thank you. I have nothing further.
MS. CONLIN: I'm done.
We'll read and sign.

THE VIDEOGRAPHER: Okay. This concludes today's deposition of Dr. Jonathan Samet.

The time is 11:01 a.m. We are off the record.

(The deposition proceedings were concluded at 11:01 a.m.)

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STATE OF CALIFORNIA)
) ss.
COUNTY OF LOS ANGELES)

I, JONATHAN SAMET, M.D., having appeared for my deposition on August 8, 2017, do this date state that I have read the foregoing deposition and that I have made any corrections, additions, or deletions that I was desirous of making in order to render the within transcript true and correct.

IN WITNESS WHEREOF, I have hereunto subscribed my name this day of , 2017.

_____
JONATHAN SAMET, M.D.

ERRATA SHEET

Case Name:
Deposition Date:
Deponent:

Pg.	No.	Now Reads	Should Read	Reason
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_____
Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME
THIS ____ DAY OF _____, 2017.

_____
(Notary Public) MY COMMISSION EXPIRES:_____

CERTIFICATE OF REPORTER

I, DORIEN SAITO, CSR 12568, CLR, a certified Shorthand reporter in and for the State of California, County of Los Angeles, do hereby certify;

That JONATHAN SAMET, M.D., the witness named in the foregoing deposition, was, before the commencement of the deposition, duly administered an oath in accordance with CCP 2094;

That said deposition was taken down in stenograph writing by me and thereafter transcribed Into typewriting under my direction.

That before completion of the deposition, review of the transcript [X] was [ ] was not requested. If requested any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am neither counsel for nor related to any party to said action, nor in any way interested in the outcome thereof.

Dated this 11th day of August, 2017.

_____
CERTIFIED SHORTHAND REPORTER
IN AND FOR THE COUNTY OF
LOS ANGELES, STATE OF CALIFORNIA

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